

ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN

FINAL REPORT

OF

PHARMACIST PRESCRIBING TASK GROUP

March 2003

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FOREWORD

This is the final report of the Royal Pharmaceutical Society of Great Britain's Pharmacist Prescribing Task Group. It addresses issues related to independent prescribing by pharmacists and precedes the imminent introduction of supplementary prescribing for the profession. The report is intended to assist the Society in its approaches to Government to continue the implementation of extended prescribing by introducing independent prescribing for pharmacists.

The Task Group believes that the timing could not be more opportune. Health Minister David Lammy M.P. stated recently at the annual dinner of the Pharmaceutical Services Negotiating Committee:

“Minor ailment clinics, repeat dispensing, supplementary prescribing and even independent prescribing all offer opportunities for you to contribute to medicines management and ensure that patients get the most out of their medicines.”

The members of the Task Group wish to acknowledge the support we have received from the President and the Council. We are also very grateful to the Wider Consultative Group members who have continued to provide valuable advice during the course of our work on independent prescribing. We also wish to record our gratitude to Barbara Stewart, who has supported the Group with efficiency, patience and good humour. While informed by the opinions of others, this final report is independent and the conclusions and recommendations are the responsibility solely of the members of the Task Group.

Dr. June Crown C.B.E.

Chairman, RPSGB Pharmacist Prescribing Task Group

SUMMARY

1. The Task Group warmly welcomes the introduction of supplementary prescribing by pharmacists and the Government's progress on implementation, and expects that this will pave the way for the introduction of independent pharmacist prescribing at the earliest opportunity. We consider that even when supplementary prescribing by pharmacists is well established, there will remain areas of clinical care which pharmacists are well able to manage. These areas form part of current practice for which pharmacists cannot currently legally accept full responsibility and accountability.
2. We strongly believe that supplementary prescribing will lead to development of services which will improve the delivery of health care to patients, achieve better clinical outcomes, and offer greater patient convenience.
3. We recommend an early start to the evaluation of supplementary prescribing, the outcomes from which could inform the development of independent prescribing. The RPSGB should offer to collaborate with this work. Information from the evaluation is expected to provide further examples of the clinical or organisational needs that independent prescribing will meet.
4. Pharmacist prescribers must participate in robust systems of clinical governance designed to meet their needs and to protect patient safety. At the request of the Task Group, the RPSGB has produced a clinical governance framework/guideline for pharmacist prescribers, which is intended to be integrated into local clinical governance arrangements.
5. Guidance on clinical governance should address concerns about the separation of prescribing and supply of medicines and should complement existing systems to ensure probity.
6. We welcome the RPSGB outline curriculum for training programmes to prepare pharmacists for supplementary prescribing and are pleased by its early uptake by a number of educational establishments. We anticipate the RPSGB continuing its work related to the training, registration and regulation of prescribing pharmacists.
7. Arrangements for the continuing education of supplementary and independent pharmacist prescribers will be necessary. Prescribing pharmacists must undertake appropriate CPD activities.
8. The Task Group believes that in the future, the demonstration of competence as independent prescribers, coupled with the responsibility for independent prescribing, will lead to greater recognition of pharmacists' skills by the public and other health professionals.

RECOMMENDATIONS

We recommend:

To the RPSGB

1. The RPSGB should confirm its support for supplementary prescribing by pharmacists, welcome the Government's progress on implementation and encourage the further extension of this service as soon as possible. (3.1, 3.4.3, 3.5.3)
2. The RPSGB should urge the Government to make an early start on the evaluation of supplementary prescribing and offer to support and collaborate with this work. (1.4)
3. The RPSGB should continue its work related to the training, registration and regulation of pharmacist prescribers. (1.5.1, 3.5.4)
4. The RPSGB should further promote its work on clinical governance for pharmacist prescribers to assist Members to establish robust systems of quality assurance and audit of their prescribing practice thus ensuring patient safety and probity. (1.5.2, 3.5.2, 3.5.4)
5. The RPSGB should press Government to continue the implementation of extended prescribing, as set out in the Review of the Prescribing, Supply and Administration of Medicines by introducing independent pharmacist prescribing at the earliest opportunity. (3.2, 3.4.2, 3.4.3, 3.5.1, 3.5.2, 3.5.3)

ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN

FINAL REPORT OF PRESCRIBING TASK GROUP

1. BACKGROUND

1.1 Terms of Reference

The Pharmacist Prescribing Task Group of the Society has worked with the following terms of reference:

- a) to establish clear policies on the roles pharmacists can play in medication therapy in the context of the NHS Plan in England* and the overarching ambitions of the profession
- b) to identify desired goals and set out and propose the tactics to achieve these goals
- c) to identify the generic competencies which would be appropriate for pharmacists (and other professions) and
- d) to be concerned primarily with pharmacist prescribing, as distinct from repeat dispensing or patient group directions.

**Early consideration to be given to the implications for Scotland and Wales.*

The Task Group, chaired by Dr. June Crown, has met on twelve occasions during 2001–2003. A list of members of the Task Group and the wider consultative group is given in Appendix 1.

1.2 General approach

The Task Group has considered the professional aspects of pharmacist prescribing such as the expected benefits to patients, through improved clinical outcomes and a more equitable service, and the benefits to pharmacists and other health professionals. We recognise that there are many other implications of the implementation of the recommendations of the Review of Prescribing, Supply and Administration of Medicines and of this report. We took the view that the Royal Pharmaceutical Society of Great Britain should reach conclusions and advise Government on professional matters, based on evidence. Decisions on implementation will have to take into account matters such as the potential economic impact and contractual issues, which are outside the responsibility and powers of the Society.

1.3 First Report of Prescribing Task Group

The Task Group originally intended to produce one report on all aspects of pharmacist prescribing. However, the Department of Health and the Medicines Control Agency (MCA) published a consultation document on supplementary prescribing by nurses and pharmacists in April 2002¹ which asked for comments by July 9th 2002. Therefore the Group prepared an initial report on supplementary prescribing to assist the

Society's Council in responding to this consultation. The first report, '**Supplementary Prescribing by Pharmacists**'² should be read in conjunction with this report. The Council accepted the report, which formed part of the Society's response to the Department of Health's consultation document (Appendix 2).

1.4 Government Action on Supplementary Prescribing

Section 63 of the Health and Social Care Act 2001 provided the legal framework for extended prescribing to other health professionals and the introduction of 'supplementary' prescribing.

The Department of Health responded to the 2002 consultation in a Ministerial statement published on November 21st. 2002. This confirmed the intention to introduce supplementary prescribing by nurses and pharmacists.

The Department of Health accepted the modified definition of supplementary prescribing proposed by RPSGB:

'A voluntary partnership between the independent prescriber and a supplementary prescriber, to implement an agreed patient-specific clinical management plan with the patient's agreement.'

It announced that training courses for pharmacists will begin in Spring 2003. It is expected that there will be up to 1000 pharmacist supplementary prescribers by the end of 2004.

The Department of Health has now issued guidance for the implementation of supplementary prescribing, 'Supplementary Prescribing by Nurses and Pharmacists within the NHS in England'³, which can be found on the Department's website (www.doh.gov.uk/supplementaryprescribing). The National Prescribing Centre has distributed a competency framework entitled 'Maintaining competency in prescribing: an outline framework to help pharmacist supplementary prescribers'⁴ (website www.npc.nhs.uk).

Further legislation to amend the Prescription Only Medicines Order and NHS regulations is expected by April 2003. This will allow supplementary prescribing by suitably trained nurses and pharmacists. Similar changes will be required in the devolved administrations.

The Department of Health is planning to undertake an evaluation of supplementary prescribing. The Task Group recommends that the RPSGB urges the Department to make an early start on this evaluation and offers to support this evaluation through membership of the project advisory group.

1.5 RPSGB Action on Supplementary Prescribing

1.5.1 Training for supplementary prescribing

The Royal Pharmaceutical Society of Great Britain has produced an outline curriculum for training programmes to prepare pharmacists for supplementary prescribing and this has been incorporated into the Department of Health's guidance. The outline curriculum is attached at Appendix 3 and can be found on the Society's website. The Society will accredit training courses at Higher Education Institutions, which are expected to consist of around 25 taught days and 12 days supervised practice. All participants will have to successfully complete the course assessment in order to be identified on the RPSGB register as an authorised prescriber.

1.5.2 Clinical Governance

The Society has prepared guidance on clinical governance for pharmacist prescribers which is attached at Appendix 4 and can be found on the Society's website. The guidance is primarily aimed at NHS organisations and all employers of pharmacist prescribers, and at individual pharmacist prescribers. It is expected to meet the requirements of pharmacist prescribers irrespective of their employer or employment setting.

2. PHARMACIST PRESCRIBING : THE CURRENT SITUATION

Several countries have introduced some form of pharmacist prescribing, though none that we are aware of has developed a system of the kind that is being proposed in the United Kingdom. Since health care systems vary considerably between countries, caution is needed in comparing the prescribing arrangements.

2.1 The United Kingdom

(see also para 3.4)

2.1.1

Pharmacists can at present:

1. 'Counter prescribe' all General Sales List (GSL) and Pharmacy (P) medicines for sale, but not issue prescriptions for supply at NHS expense.
2. Issue emergency supplies of some Prescription Only Medicines (POMs).
3. Supply and administer certain products through Patient Group Directions at public expense, some of which could be POMs.

Pharmacists will soon be able to:

Be supplementary prescribers and, within a patient specific clinical management plan, prescribe on NHS prescriptions at public expense. There will be no restriction on the range of medicines or conditions, provided the guidance and agreed clinical management plan are followed. In the first instance, controlled drugs and certain unlicensed medicines will be excluded.

Pharmacists cannot at present:

Independently prescribe POMs, within or outside the NHS.

A number of pilot schemes for management of minor or common ailments by pharmacists, involving 'prescribing', have taken place throughout the UK, for example, in: *Arbroath, Croydon, Derby, Hull, Sheffield, Sefton, Somerset, Tyne and Wear, Wiltshire*. These 'Direct Supply' schemes have been evaluated to varying degrees⁵ and several are described in Appendix 5, together with Scotland's Direct Supply of Medicines Scheme.

The schemes have followed different models, featuring some of the following:

- *agreed list of self-limiting minor or common conditions*
- *local formularies agreed between participating GP practices and community pharmacies – mostly for products for symptomatic relief of listed conditions*
- *referral procedures: patient self-referral, referral by practice staff or by community pharmacist*
- *voluntary patient registration with a scheme*
- *use of vouchers or prescription forms completed by community pharmacists*
- *provision of a quiet area or consultation area within the pharmacy*
- *funding arrangements: annual fee, monthly retainer, per capita fee, dispensing fee or a fee per consultation; plus reimbursement for the medicines supplied*
- *steps embedded in schemes to ensure probity and safety.*

While recognising the small scale of these pilot projects, some schemes have been extended to cover whole primary care trust (PCT) areas in England. Other schemes have incorporated Patient Group Directions to increase the range of prescribable products.

A Sefton-based intervention study^{6,7} has evaluated the outcomes of removing economic barriers to self-care, arising from prescription charge exemption. The scheme enabled the transfer of the workload for 12 common or minor conditions from one general practice to eight community pharmacies. Most of the consultations were for three of the conditions; head lice, vaginal thrush and upper respiratory tract infections. The overall costs of the pharmacy scheme were not substantial; overall prescribing costs did not increase.

A self-care scheme in Tyne and Wear⁸ involved patients seeking appointments with their GP for respiratory tract infections, gastrointestinal problems, hay fever and thrush being directed to their local pharmacy. Pharmacists were able to prescribe from a locally agreed formulary, which included some POMs.

2.1.2 Scotland

The Scottish pharmaceutical care strategy 'The right medicine'⁹ was published last year with a completion date of 2005 for the 60 action points contained in it. One point already taken forward relates to pharmacist prescribing.

In Scotland, the 'Direct Supply of Medicines Scheme'¹⁰ has enabled patients exempt from prescription charges to consult a community pharmacist and receive advice and treatment with OTC medicines, free of charge under the NHS. The generally positive experience from this pilot, plus further extended monitoring¹¹ has informed an imminent, wider roll-out of the scheme throughout two Health Boards.

2.1.3 Wales

'Remedies for success: a strategy for pharmacy in Wales'¹² published in September 2002, states that pharmacists can move to full independent prescribing status as quickly as legislative change permits. One action point reads:

"The Welsh Assembly Government is already committed to the extension of supplementary prescribing rights to pharmacists by 2004. It is hoped that independent prescribing status will follow."

2.2 Other European Countries

A number of European countries, including Denmark, Holland and Sweden, have a long history of reclassification of licensed medicines from prescription only to OTC status. In Denmark, hydrocortisone ointment 1% has been available to the public as an OTC product since 1984, and cimetidine and ranitidine since 1989. However, formalised pharmacist prescribing, as identified in this report, has not been developed or introduced in Europe to date.

2.3 United States of America

In 2001, pharmacists had prescribing rights in 25 States, most of which require protocols agreed with a physician, a form of 'dependent' prescribing. This may include authority to adjust dosages, order laboratory tests, perform physical assessments and administer medication. Schools of pharmacy now include physical assessment skills in their curricula. In Florida there is a form of 'independent' prescribing by pharmacists, from a limited formulary and prescription-only strengths of non-prescription medicines may be sold without a physician's prescription. However few

patients or pharmacists take advantage of the law because of the burden of record keeping required.

It has been suggested that one of the biggest challenges to pharmacist prescribing in the US has come from the pharmaceutical industry¹³. There is concern that a shift in prescribing authority could lead to a loss of influence on drug choice, and fears that pharmacists would be more likely than existing prescribers to prescribe generic products.

2.4 Australia and New Zealand

No evidence about pharmacist prescribing was found in an extensive literature search and there is no current legislation allowing pharmacist prescribing.

3. FURTHER DEVELOPMENT OF PHARMACIST PRESCRIBING

The Task Group welcomes the rapid progress that is being made in the implementation of supplementary prescribing for pharmacists. We believe that this will form a sound basis for the introduction of independent prescribing, which has the potential to further improve clinical outcomes and patient convenience.

3.1 Expected benefits of supplementary prescribing by pharmacists.

The benefits to patients from supplementary prescribing will depend on the way it is interpreted and regulated by Government, and how it is implemented and practised by pharmacists. The Review of Prescribing, Supply and Administration of Medicines¹⁴, envisaged *dependent* (supplementary) prescribing being offered in association with independent clinical management of patients with an established diagnosis. The guidance recently published by the Department of Health indicates that this will be the case, and that the arrangements for clinical management plans will be straightforward and not unnecessarily burdensome.

Supplementary prescribing by pharmacists should then offer many opportunities to improve clinical care. In addition to the obvious enhancement of access to services and greater convenience for patients, there is the potential to improve clinical outcomes and contribute to the achievement of the goals set out in the National Service Frameworks. We expect improvements in the prevention of disease, the management of long term conditions and the organisation of patient care.

3.1.1 Health Promotion and Disease Prevention

Supplementary prescribing by pharmacists should improve the uptake of treatments such as statins and aspirin for the prevention of coronary heart disease and calcium supplements to delay osteoporosis.

3.1.2 Management of Long Term Conditions

Partnership in the monitoring and management of long term conditions, such as hypertension and some forms of mental illness, and continuing treatment, such as anti-coagulant therapy, will offer more consistent supervision linked with easier access to a professional opinion. This should result in more rapid identification of problems and swifter changes in management to help reduce complications or deterioration in the clinical condition and health status of the patient. An enquiry into primary care dermatology services¹⁵ has welcomed supplementary prescribing initiatives, which will benefit sufferers from chronic skin diseases.

3.1.3 Support for the 'Expert Patient'

An estimated 17.5 million adults living in Great Britain suffer from a long-term condition¹⁶. Patients with long-term conditions will find their clinical needs easier to manage, with an increased choice of care arrangements available to them. Newly diagnosed patients will benefit from detailed advice on the medicines and other care that they need, the range of products available and their advantages and disadvantages.

3.1.4 Rapid response to exacerbations of relapsing conditions

Flexible clinical management plans would enable patients with relapsing conditions such as gout to obtain rapid treatment from a pharmacist at the onset of an acute episode of their disease.

3.1.5 Reducing Inequalities

Easier geographic and temporal access to services within familiar surroundings should assist people who tend to underuse services to make better use of available care, to take medicines more regularly and to obtain them through the NHS.

3.2 Independent Prescribing

The benefits of supplementary prescribing by no means exhaust the potential contributions of pharmacist prescribers. The Task Group, after careful discussion, concludes that the RPSGB Council should press the Government to develop plans for the introduction of independent pharmacist prescribing.

The Group accepts the definition of an independent prescriber proposed by the Review of Prescribing, Supply and Administration of Medicines :

a professional who ***"is responsible for the assessment of patients with undiagnosed conditions and for decisions about the clinical management required, including prescribing."***

However, as experience of supplementary prescribing is gained, it may be necessary to review whether the current definitions of independent

and supplementary prescribing encapsulate all the circumstances where prescribing by pharmacists can benefit patients and the NHS.

3.3 Independent prescribing by nurses

The experience gained by nurses in the implementation of independent prescribing will help the RPSGB and individual pharmacists in developing plans and programmes.

Since 1992 suitably trained district nurses and health visitors have been able to prescribe from items listed in the Nurse Prescribers' Formulary (NPF). By September 2001, more than 22,000 district nurses and health visitors, including around 1000 practice nurses holding one or more of these qualifications, had completed training.

In March 2002, the Department of Health introduced an implementation strategy for the extension of independent nurse prescribing within the NHS in England¹⁷. Other groups of nurses are now being trained to prescribe independently from a wider range of medicines. These will include all GSL and P medicines and a list of POMs linked to specific medical conditions in four areas:

- minor illness
- minor injuries
- health promotion and maintenance
- palliative care.

Both the Nurse Prescribers' Formulary for District Nurses and Health Visitors and the Nurse Prescribers' Extended Formulary are set out in current editions of the British National Formulary¹⁸. The Department of Health and MCA plan to consult on extension of the Extended Formulary over the next year.

3.4 Independent prescribing by pharmacists

3.4.1 The current situation.

The current authority of pharmacists in relation to prescribing is summarised in paragraph 2.1.

A pharmacist working in registered premises can supply to the public any General Sales List (GSL) or Pharmacy (P) medicine. In community practice, therefore, pharmacists are already acting as 'independent prescribers', in that they assess the patient's problem, advise on management and supply an appropriate medicine, all with the patient's agreement. The pharmacist is fully responsible and accountable for his or her actions in this process, including omissions and failure to refer the patient to a doctor when necessary. However the pharmacist can only sell the recommended product to the patient and cannot supply it on an NHS prescription to be paid for from public funds. Many former Prescription Only Medicines (POMs) have been reclassified to P or GSL status so that the range of clinical conditions for which the pharmacist can supply an appropriate medicine has increased considerably. This process of reclassification is expected to continue.

In addition, pharmacists are now taking a greater role in health promotion and disease prevention efforts, for example by issuing emergency contraception ('morning after pills') to reduce unwanted pregnancies, and nicotine replacement therapy to assist smoking cessation.

3.4.2 The Clinical Case for Independent Prescribing by Pharmacists

All the benefits of supplementary prescribing can be built upon by the extension of independent prescribing rights to pharmacists.

In particular, this would allow a much greater contribution by pharmacists to acute care:

a. Hospital Practice

Pharmacists are already recognised as important members of clinical teams. Their knowledge of pharmacology and pharmacokinetics enables them to identify and deal with many of the medicine related iatrogenic problems that present in hospitals and their intervention to alter or to stop medicines can be life saving.

Their independent contributions to care could include:

- Taking responsibility for pre-admission assessment of medicines
- Dealing with discharge medication
- Dealing with emergency admissions that are related to medicines.

b. Community Based Practice

An extended formulary for independent pharmacist prescribing which gave pharmacists access to certain POM medicines would allow them to deal rapidly and effectively with many acute conditions such as acute asthma, urinary tract infections and some skin conditions. An approach similar to that used for the introduction of extended nurse prescribing would be a valuable measure, which could be extended as experience and confidence increased.

Pharmacists increasingly undertake independent sessions in primary care centres in which they should be able to take full responsibility for the clinical decisions they take, rather than being obliged to seek a doctor's endorsement.

In addition, community based pharmacists are particularly well placed to contribute to prevention programmes and health promotion through advice support, which should be accompanied by the authority to prescribe when needed.

3.4.3 The Policy Case for Independent Pharmacist prescribing

The Government is committed to reducing inequalities in all areas and the NHS is expected to make its contribution to this. The present arrangements for pharmacist 'prescribing', whereby people can purchase P and GSL medicines but cannot obtain them from a pharmacist at public expense through an NHS prescription is inequitable. As an interim

measure, this could be addressed by allowing pharmacists to supply these medicines at public expense, at least to those patients who are exempt from prescription charges. However, the best approach would be the introduction of independent pharmacist prescribing which would achieve the clinical benefits outlined above as well achieving better and more convenient access to timely care for the most vulnerable people.

A further development in primary care has been Government support for moves to transfer the burden of common or minor ailments from general medical practitioners to other community-based health care professionals, as exemplified by the development of NHS Direct¹⁹. Independent pharmacist prescribing can contribute to demand management of common or minor ailments.

3.5 Implications of Independent Prescribing by Pharmacists

3.5.1 Implications for patients

- a. Rapid access to care from an appropriate and responsible professional for medication related problems.
- b. Timely intervention which will reduce the impact of disease.
- c. Improved access to care for vulnerable people.

3.5.2 Implications for professionals

a. Clear professional accountability

The independent pharmacist prescriber would have the same sole responsibility and accountability for patient care that they have at present in relation to 'counter prescribing'. Possible uncertainties about accountability that might arise with supplementary prescribing would be eliminated

b. Better use of professional skills

The pharmacist's detailed knowledge of medicines would be more directly applied to the clinical management of patients and the treatment of medication related difficulties.

c. Better recognition of pharmacists' skills

The demonstration of competence as independent prescribers and acceptance of responsibility for independent prescribing will lead to greater recognition of pharmacists' skills by the public and other health professionals. The British Medical Association has already signalled its support for independent prescribing by pharmacists, on condition that they have the necessary skills and are prepared to take personal responsibility for their actions²⁰.

3.5.3 Implications for the NHS

- a. Improved care of patients.
- b. Improved access and convenience for patients
- c. Better use of the professional skills of pharmacists
- d. Reducing the burden on other health professionals

- e. Improved professional teamwork
- f. More efficient use of resources
- g. Reduced delays in hospitals
- h. More effective support for programmes to achieve NSF goals.

3.5.4 Implications for Professional Organisations

The pharmacy profession must develop standards of practice for pharmacist prescribers that ensure patient safety and probity. The requirements are largely the same for independent and supplementary prescribing.

- a. Pharmacists must only act within their competence
- b. They must acquire and retain the clinical skills needed for the assessment of the patient.
- c. They must acquire and retain the pharmaceutical skills necessary for safe prescribing.
- d. They must establish and participate in appropriate systems of audit and clinical governance.
- e. They must undertake appropriate CPD activities
- f. Concerns about the loss of separation of prescribing and supply of medicines must be addressed. In the context of supplementary prescribing, the clinical management plan, good practice in checking the accuracy of dispensing and the existing audit mechanisms provide adequate protection.

The evidence about the frequency of prescribing errors that are identified and corrected by pharmacists before dispensing highlights the need for double checking of prescriptions of all independent prescribers wherever possible. In the case of independent pharmacist prescribing, particularly in community settings, this could hamper improvements in access. It is however essential that patient safety is protected at all times, so robust systems must be devised that satisfy the concerns of the profession, other health professions, the public and decision makers.

4. CONCLUSIONS

The rapid introduction of supplementary prescribing by pharmacists will provide opportunities to introduce new services, which will improve services to patients, achieve better clinical outcomes, and offer greater patient convenience. There will also be benefits to pharmacists, whose skills will be better used and recognised.

Even when supplementary prescribing by pharmacists is well established, there will remain areas of clinical care, which they are well able to manage

and which form part of current practice, but for which they cannot currently legally accept full responsibility and accountability.

Information from the evaluation of supplementary prescribing is expected to provide further examples of the clinical or organisational needs that independent prescribing will meet.

The Task Group believes that the RPSGB should therefore continue to press Government to take forward the recommendations of the Review of Prescribing, Supply and Administration of Medicines regarding independent prescribing and to build on the experience of pharmacists in this area without further delay.

5. RECOMMENDATIONS

5.1 The RPSGB should confirm its support for supplementary prescribing by pharmacists, welcome the Government's progress on implementation and encourage the further extension of this service as soon as possible. (3.1, 3.4.3, 3.5.3)

5.2 The RPSGB should urge the Government to make an early start on the evaluation of supplementary prescribing and offer to support and collaborate with this work. (1.4)

5.3 The RPSGB should continue its work related to the training, registration and regulation of pharmacist prescribers. (1.5.1, 3.5.4)

5.4 The RPSGB should further promote its work on clinical governance for pharmacist prescribers to assist Members to establish robust systems of quality assurance and audit of their prescribing practice thus ensuring patient safety and probity. (1.5.2, 3.5.2, 3.5.4)

5.5 The RPSGB should press Government to continue the implementation of extended prescribing, as set out in the Review of the Prescribing, Supply and Administration of Medicines by introducing independent pharmacist prescribing at the earliest opportunity. (3.2, 3.4.2, 3.4.3, 3.5.1, 3.5.2, 3.5.3)

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ROYAL PHARMACEUTICAL SOCIETY RESPONSE

CONSULTATION DOCUMENT MLX 284

Proposals for supplementary prescribing by nurses and pharmacists and proposed amendments to the Prescription Only Medicines (Human Use) Order 1997

The Royal Pharmaceutical Society concurs with the intent of the proposals contained in MLX 284: to enhance patient care by providing quicker and more efficient access to healthcare through an increased and flexible use of nurses' and pharmacists' skills, and the expectation of rapid progress in implementation. The Society welcomes the opportunity to respond to the consultation document and offers the following comments:

1. *Proposals to amend the POM Order (para 3)*

We strongly support the proposals to amend the POM Order to enable supplementary prescribers to prescribe POM medicines, as part of a clinical management plan for an individual patient, throughout the UK. We recognise that the extent to which supplementary prescribing is adopted within the NHS in devolved administrations will be a matter for each of the separate administrations.

2. *Application outside the NHS (para 4)*

We support the introduction of supplementary prescribing outside the NHS but recommend that it is made clear that patients treated outside the NHS in private practice may not be issued with NHS prescriptions, in line with current arrangements.

3. *Supplementary prescribing – proposed working definition (para 8)*

The following concise definition of supplementary prescribing is recommended:

'A voluntary partnership between the independent prescriber and a supplementary prescriber, to implement an agreed patient-specific clinical management plan with the patient's agreement.'

This provides a clear description of the essential characteristics of supplementary prescribing. The word 'responsible', describing the independent prescriber in the consultation document's definition is not necessary in the context of a professional partnership in which both participants accept responsibility for patient care. The definition does not need to include the possible clinical situations suitable for supplementary prescribing, as this could imply that other appropriate service developments should be excluded.

4. Supplementary prescribers (para 9)

All registered pharmacists should be considered potential supplementary prescribers, while recognising that the priority for public funding of prescribing training should be determined by the needs of patients and of clinical services. In the future we think that the core training for prescribing should be incorporated into the undergraduate MPharm curriculum, with registration as a prescriber being achieved after successful completion of a period of competency based supervised practice.

5. Proposed Principles of supplementary prescribing (para 10)

The Society endorses the first six principles of supplementary prescribing set out in Paragraph 10, but we disagree with the seventh (final) principle.

We consider that the **separation of the prescribing and supply of medicines** is no longer necessary to maintain patient safety and good governance. We expect all pharmacist prescribers to participate in an approved programme of clinical governance, which establishes sound systems for patient safety. Concerns about other aspects of governance are met by the presence of adequate audit arrangements.

We suggest that the point on **access to records** should be clarified and strengthened to state:

'all prescribers must have access to the patient's clinical and medication records'.

We recognise that there may be rare instances when it might be justified for some parts of the medical record to remain confidential to the independent prescriber. However, we consider that all health professionals who are responsible enough to be registered prescribers should be assumed to understand fully the requirements for confidentiality.

We also consider that the regulatory bodies will be able to deal appropriately with any instances of professional misconduct.

The use of patient-held records would ensure that the patient consented to the transfer of information between prescribers. Patients who do not wish information about their medical state to be accessible to supplementary prescribers may prefer to remain under the sole care of the independent prescriber.

6. The proposed legislative requirements (para 11)

We support the proposed legislative requirements but think it essential to provide a clear definition of 'clinical management plan' for hospital and for community-based services.

It is our view that a clinical management plan for the large number of patients crossing the interface in and out of hospital has to be derived from the clinical team's work (see point 9 below), where the prescribing plan is reflected in the in-patient prescribing chart, modified at discharge to take account of hospital and directorate agreed guidelines.

7. Clinical conditions and medicines to be included in supplementary prescribing (paras 12 to 17)

The Society strongly supports the proposal that the no legal restrictions should be placed on the range of medicines (with the exception of controlled drugs and unlicensed medicines outside paediatric care) or clinical conditions for supplementary prescribing. We think that any such limitations would significantly reduce the contributions of supplementary prescribing to improved patient care.

Whilst we agree that normally, the use of medicines should be consistent with the Summary of Product Characteristics for the relevant product, we suggest that there should be flexibility in the inclusion of medicines used outside their licensed indications. We agree that it is essential in paediatric practice. The use of off-licence medicines should also be allowed if it is agreed by both prescribers. Similarly, we agree that products which are "less suitable for prescribing" should be included if their use is agreed by both prescribers as being in the patient's best interest.

We hope that controlled drugs will be included as soon as possible so that the range of care suitable for supplementary prescribing can be extended to include patients who need expert pain control.

8. Scope of the clinical management plan (paras 18, 19)

We endorse the proposals for the clinical management plan subject to the inclusion of a clear definition of such a plan. In addition, we recommend that there should be more detailed guidance on the criteria for the plan, for instance, that it should be evidence based and consistent with recognised clinical guidelines; that it should be agreed by prescribers and the patient and, where appropriate, the carer or parent; and there should be explicit arrangements for systematic review.

9. Prescribing partnerships (paras 20 to 22)

We think that restriction of supplementary prescribing to partnerships of one named independent prescriber and one named supplementary prescriber is incompatible with continuing patient care and would severely limit the usefulness of supplementary prescribing to patients, professionals and the health service. The prescribing partnership must recognise that patient care is largely delivered by teams, in both hospital and community-based practice.

In hospital practice, the independent prescribers could be a specified medical team, with responsibility in the hands of the consultant head of that team or a

nominated deputy. The supplementary prescribers could be identified pharmacists with training and experience appropriate to the clinical area concerned, nominated by the hospital Chief Pharmacist. In community practice the independent prescribers could be a group of general practitioners agreed by the practice and/or the Primary Care Organisation. The supplementary prescribers could be nominated pharmacists approved by the PCO pharmacy advisor. In all cases the individual patient must agree to the arrangements. We recognise that these ideas introduce complexity into the system, but fear that undue simplicity will not achieve the stated aims of supplementary prescribing.

10. Roles and responsibilities of independent and supplementary prescribers (paras 23, 24)

The Society agrees with the summary of responsibilities of independent and supplementary prescribers, though we see the partnership as mutually supportive, not just the independent prescriber supporting the supplementary prescriber colleague.

It is envisaged that a supplementary prescriber will be able to vary the dosage, frequency or formulation of a medicine, or to prescribe a different drug to the patient, as appropriate to the patient's condition and within the limits of an identified clinical management plan. The competencies needed by pharmacists will depend on the focus of the supplementary prescribing. These will encompass: clinical assessment and diagnostic skills; and professional competencies such as critical appraisal skills. Pharmacists' baseline pharmaceutical competencies are already established in: pharmacology, pharmacokinetics, drug interactions, adverse effects of drug therapy, dosage and contraindications to specific treatments.

Pharmacists are well placed, especially as supplementary prescribers, to act for the benefit of patients in matters relating to compliance and concordance. They can identify medication-related problems. Their expertise in these areas, which is recognised by the public, and their accessibility, enhance their ability to assess and facilitate concordance.

The National Prescribing Centre's document, 'Maintaining Competency in Prescribing' contains a framework for continuing education for existing nurse prescribers. About 70% of the competencies are 'core' and relevant for prescribers of all professional backgrounds. The Society is pleased to note that the Department of Health has commissioned the National Prescribing Centre to develop a competence framework for pharmacists based on the current nurse prescribing competence framework.

We note that the NPC is also helping to identify:

- issues about how supplementary prescribing will work in practice e.g. development of a clinical management plan, working in teams, communication between prescribers. This would then inform any additional

preparation and training needed by the current extended independent nurse prescribers.

- what, if any, training independent prescribers may need to enter into a supplementary prescribing partnership, and
- competencies for supplementary prescribers particularly for pharmacists.

11. Training and preparation (paras 25 to 27)

We envisage that the professional partnership between independent and supplementary prescribers will be mutually supportive and that training for this role will be undertaken jointly. It is likely that the same core training will be needed for independent and supplementary prescribing and that the introduction of extended prescribing offers exciting opportunities for multidisciplinary education and training in the core modules.

We have made a number of assumptions about the training needs for prescribing pharmacists. Firstly, that pharmacists will ultimately undertake independent as well as supplementary prescribing. Secondly, that in response to that extension to the scope of practice of pharmacists, the undergraduate course and pre-registration programme will incorporate the necessary additional knowledge and skills required. This leads us to believe that necessary additional educational and training needs to be considered in three phases:

- Modifications and additions to the M.Pharm. degree and pre-registration year* – this aspect is beyond the remit of this consultation but is being taken forward by the Education Committee of the RPSGB.
- Top up training for those currently studying for the MPharm degree or in their pre-registration year* – this group could rapidly undertake the additional necessary training, provided the undergraduate course and pre-registration period include appropriate and adequate clinical training plus some supervised practice.
- A comprehensive programme of preparation for longer serving pharmacists* – to contain specific content aimed at revising, updating and extending knowledge in aspects of pathophysiology and pharmacology. Importantly, this programme must be based on generic competencies identified as necessary for good prescribing practice.

We see the Society's main role as the regulatory and professional body for pharmacy, as accrediting pharmacists who have demonstrated their supplementary prescribing competency, and defining and accrediting the education and training for pharmacist prescribers.

We expect that the education, training and continuing professional development of independent prescribers will in future match that being developed for new prescribers and that courses will be shared where

possible. We also suggest that training for prescribing partnerships should involve all participants, not just the independent prescribers.

12. Nurse prescribing

In framing our responses we considered the principles of supplementary prescribing in relation to both nurse and pharmacist supplementary prescribing. We have not set out to reply to technical points on nurse prescribing in the consultation document, as we believe others will be in a better position to respond in this respect.

We hope our comments will be informative and helpful to the supplementary prescribing consultation process. The Society would be pleased to respond should you wish to discuss or explore further any of the points we have made.

ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN
PHARMACIST PRESCRIBING TASK GROUP

FIRST REPORT

SUPPLEMENTARY PRESCRIBING
BY PHARMACISTS

July 2002

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FOREWORD

This is an interim report from the Royal Pharmaceutical Society of Great Britain's Pharmacist Prescribing Task Group. It addresses issues related to the introduction of supplementary prescribing by pharmacists and is intended to assist the Society in the preparation of its response to the Government's consultation document on this subject.

The members of the Task Group wish to acknowledge the support we have received from the President and the Council. We are also very grateful to the Wider Consultative Group members who have provided valuable advice during the course of our work. While informed by the opinions of others, the report is independent and the conclusions and recommendations are the responsibility solely of the members of the Task Group.

We wish to thank Barbara Stewart, who has worked extremely hard in support of the Task Group and has ensured that we meet our deadlines.

We shall produce our final report, which will address the issues of independent prescribing by pharmacists, by the end of 2002.

Dr. June Crown C.B.E.

Chairman, RPSGB Pharmacist Prescribing Task Group

SUMMARY

1. The Task Group warmly welcomes the progress towards supplementary prescribing by pharmacists and expects that this will pave the way for the rapid introduction of independent prescribing. We strongly believe that this will provide benefits to patients and to health services and will make better use of the skills of pharmacists.
2. We believe that all registered pharmacists should be eligible to become prescribers but recognise that implementation will have to be staged, with priority for training being determined by the needs of the service.
3. We recommend that all pharmacist undergraduate programmes should in future include prescribing in the curriculum.
4. We welcome most of the proposals in the Department of Health and Medicines Control Agency consultation document on supplementary prescribing by nurses and pharmacists.
5. We expect adequate resources to be made available for the introduction and subsequent continuing provision of supplementary prescribing services.
6. We recommend an amended definition of supplementary prescribing:
'A voluntary partnership between the independent prescriber and a supplementary prescriber, to implement an agreed patient-specific clinical management plan with the patient's agreement.'
7. We look for a clear definition of 'clinical management plan' and the establishment of criteria for such plans. They should be designed to ensure patient safety but should avoid unnecessary complication that would deter practitioners from establishing a supplementary prescribing service. They should be evidence based and in line with recognised clinical guidelines.
8. We consider that the proposed supplementary prescribing partnership between an individual independent prescriber and an individual supplementary prescriber is unrealistic and would diminish the benefits to patients. Proposals should recognise that clinical care is usually provided by teams of health professionals.
9. Safe and effective prescribing depends on full access to clinical and medication records by all prescribers. Interim arrangements may be necessary until the Department of Health's information strategy is fully implemented.
10. The introduction of supplementary prescribing is intended to improve the range of services available to patients. It must however be made clear that it is optional and that patients can choose whether to use this service or remain under the sole care of their independent prescriber.
11. Pharmacist prescribers must participate in a system of clinical governance designed to meet their needs and to protect patient safety. The accuracy of a prescription should be checked by a suitably trained colleague who does not necessarily have to be a registered pharmacist.
12. Educational establishments will have to work with others to develop programmes for prescribing training for qualified pharmacists and should be prepared to introduce prescribing training into the undergraduate curriculum.

13. Arrangements for the continuing education of pharmacist prescribers will be necessary and could with advantage be multidisciplinary.
14. The RPSGB, as the registration and regulatory body, will have to make arrangements for the identification of eligible prescribers on the register.

RECOMMENDATIONS

We recommend:

To the Department of Health

1. The definition of supplementary prescribing be amended to read:
'A voluntary partnership between the independent prescriber and a supplementary prescriber, to implement an agreed patient-specific clinical management plan with the patient's agreement.' (3.2.2)
2. In principle, all registered pharmacists should be eligible to train as supplementary prescribers, but acknowledge at the outset that there will be limited training capacity. The priority for public funding of prescribing training should be determined by the needs of patients and clinical services. (3.3.3)
3. The prescribing partnership must have as a prerequisite an agreement on access to records and clear arrangements for sharing information. (3.5.1)
4. Serious consideration should be given to the introduction of patient held records, available throughout the NHS for those patients who wish to participate. (3.5.3)
5. There should be a clear definition of a 'clinical management plan' and more detailed guidance on the criteria for the plan. (3.8.v)

To the RPSGB

6. The RPSGB should develop national standards for clinical governance programmes designed to meet the specific needs of all supplementary prescribers. (3.7.3, 3.7.4, 3.7.5)
7. The RPSGB, working with the Department of Health, Schools of Pharmacy and the universities should be asked to draw up appropriate course and programme specifications to meet the needs of pharmacists and pharmacy undergraduates. (4.4)
8. The RPSGB should work with the Department of Health to enable the timely development of a competency framework for pharmacist supplementary prescribing. (3.4, 4.6, 4.7, 4.8)

9. The RPSGB, with educational establishments, should develop criteria for the demonstration of ongoing competence as part of CPD for prescribing pharmacists. (4.9)

10. The RPSGB should work with the national Centres for Postgraduate Pharmacy Education as well as the Schools of Pharmacy and universities, to develop novel approaches to CPD for prescribing pharmacists. (4.10)

11. The RPSGB should consider drafting an appropriate byelaw to allow a separate indication or annotation of the Register of Pharmaceutical Chemists to record the prescribing status of registered pharmacists. (5.2)

To the NHS and Higher Educational Funding Councils

12. The Workforce Development Confederations of the NHS (in relation to training for pharmacists) and the Higher Education Funding Councils (for pharmacy undergraduates) be requested to consider resource implications for the education and training requirements, and provide the necessary funding support. (4.13, 4.14)

1. Background and Context

Extending the Authority to Prescribe

- 1.1 The Review of Prescribing, Supply and Administration of Medicines (final report March 1999¹) recommended that the authority to prescribe should be extended beyond existing prescribers (doctors, dentists and some nurses) to other groups of suitably trained and experienced health professionals. The Review also recommended that there should be two groups of prescribers, 'independent' and 'dependent' (now termed 'supplementary'). The independent prescriber is the person who is responsible for the initial clinical assessment and preparation of a plan for the clinical management of an individual patient. The supplementary prescriber can take responsibility for the management of a patient who has been assessed by the independent prescriber.
- 1.2 The recommendations of the Review were broadly welcomed by the health professions and were accepted by Government. Legislation to implement the Review Team's recommendations was passed through Parliament in the Health and Social Care Act in 2012².

The Pharmacist Prescribing Task Group

- 1.3 The Royal Pharmaceutical Society of Great Britain welcomes the Government's support for extending the authority to prescribe to more groups of health professionals. It expects that pharmacists will be among the first groups of new prescribers and wishes to contribute constructively to the planning and preparation for this development in health care.

The Society therefore established a task group in May 2001 with the following terms of reference:

- a) to establish clear policies on the roles pharmacists can play in medication therapy in the context of the NHS Plan in England* and the overarching ambitions of the profession
- b) to identify desired goals and set out and propose the tactics to achieve these goals
- c) to identify the generic competencies which would be appropriate for pharmacists (and other professions) and
- d) to be concerned primarily with pharmacist prescribing, as distinct from repeat dispensing or patient group directions.

**Early consideration to be given to the implications for Scotland and Wales.*

- 1.4 The Task Group is chaired by Dr. June Crown and includes pharmacists, other health professionals, educationalists and patient representatives. The Group is supported by a wider consultative group with a broader membership. The members of this group are available for advice and meet with the Task Group from time to time. Officials from the UK Departments of Health attend meetings of the Task Group as participating observers. A list of members of the Task Group and the wider consultative group is given in Appendix 1.
- 1.5 The legislation relating to extended prescribing applies across the whole of the UK and we consider that the competency base will be the same for all new pharmacist prescribers. We recognise, however, that devolved administrations may develop different models of service within the NHS in each country. Although ideally it would be helpful for the roll out of supplementary prescribing by pharmacists to be similar throughout the UK, this may not necessarily be the way it is taken forward. We are grateful to members of the consultative group from Scotland and Wales who have advised on these issues.
- 1.6 The Task Group originally intended to produce one report on all aspects of pharmacist prescribing by the end of 2002. However, the Department of Health and the Medicines Control Agency published a consultation document on supplementary prescribing by nurses and pharmacists in April 2002³ which asks for comments by July 9th 2002. It was therefore agreed that the Group would prepare an initial report on supplementary prescribing to assist the Society's Council in responding to this consultation.

2. The Present Situation and the Role of Pharmacists in the UK

2.1 Categories of Medicines (POM, P, GSL)

The legislative requirements relating to the prescribing, supply and administration of medicines in the UK are set out in the Medicines Act 1968⁴, and in secondary legislation made under the Act. Legislation on the reimbursement of medicines under the NHS is derived from the NHS Act 1977⁵.

At present, medicines are divided into three categories (their legal status), depending mainly on the dangers they pose and the risk of misuse.

General Sales List (GSL) medicines may be sold or supplied from any lockable premises.

Pharmacy medicines (P) may only be sold or supplied by or under the supervision of a pharmacist from registered premises, although there are some exemptions.

Prescription Only Medicines (POM) have had an additional restriction in that they could, until recently, only be supplied by a pharmacist against the prescription of an 'appropriate practitioner', i.e. doctors, dentists and some nurses.

In August 2000, legislation on Patient Group Directions (PGDs) was enacted. This allows medicines, which may include POMs, to be supplied and/or administered under the NHS to categories (groups) of patients in accordance with written instructions that have been agreed by a doctor, a pharmacist and other relevant professionals and approved by the relevant service manager. With respect to future developments, PGDs are to be extended to private, charitable and voluntary sector hospitals and to prisons, police custody suites and the defence medical services. Care homes are excluded from the proposed extension. The criteria for PGDs in the new sectors will be largely the same as for NHS PGDs.

2.2 The Dispensing and Supply of Medicines

Prescription only medicines may only be supplied by a pharmacist against the prescription of an 'appropriate practitioner' (see above). 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 such as checking the validity of the prescription, the appropriateness of the medicine for an individual patient and assembly of the product. In common usage *dispense* is usually reserved for the activity of pharmacists and dispensing doctors. *Supply* is taken to mean providing a medicine directly to a patient or carer.

2.2.1 *Repeat Dispensing and Repeat Prescribing*

'Primary care pharmacists' work in GP practices where amongst other things they undertake pharmacist-directed medication reviews. Some of them have participated in 'repeat dispensing' initiatives, which vary in detail but not in principle. These have contributed to the evidence base on which to develop proposed supplementary prescribing models^{6,7}. Many community pharmacists are also involved in repeat prescribing and dispensing initiatives.

2.2.2 *Instalment Dispensing*

The provision of services to drug misusers through community pharmacies has expanded to meet the increasing need⁸. This can include 'instalment dispensing' (especially in Scotland) and supervision of patient self-administration of methadone.

2.2.3 *Emergency Supply*

In an emergency, a person lawfully conducting a retail pharmacy business can sell or supply a POM when certain conditions are satisfied. This may be at the request of a doctor or of a patient. A doctor who is unable to furnish a prescription immediately may request an emergency supply and must undertake to provide the prescription within 72 hours. If a patient requests an emergency supply, the pharmacist has to be satisfied that there is a genuine emergency, that a prescription cannot be obtained in the normal way, and that the POM requested has been prescribed by a doctor on a previous occasion for that patient. (Controlled drugs are excluded from emergency supplies, with the exception of phenobarbitone in the treatment of epilepsy.)

2.2.4 *Patient Group Directions*

Legislation also permits the supply of POMs under patient group directions (PGD). A PGD is a written direction relating to the supply and/or administration of a POM to a group of people, which is signed by a doctor or dentist, a pharmacist and other relevant practitioner. There are three main types of PGD, all of which could involve pharmacists.

- i. Authorised healthcare professionals may supply medicines on behalf of an NHS body.
- ii. PGDs may be used to assist an independent prescriber to provide primary care NHS services.
- iii. An NHS body may approve a PGD for the supply of a POM by a pharmacist from a community pharmacy.

2.3 Training, education, continuing professional development

2.3.1 Following graduation in pharmacy from a university-based school of pharmacy, a pharmacy graduate must successfully complete a period of preregistration training. This is patient-focused, encompasses performance standards, and involves

wide-ranging experience of professional practice, which is supervised by a work-based tutor.

- 2.3.2 Registered pharmacists are required to maintain their skills and knowledge. Currently, each year they must undertake a minimum of 30 hours of continuing education, which is structured to meet their personal needs. A continuing professional development (CPD) framework has been developed by RPSGB, which will support the implementation within the next three to five years of a mandatory CPD requirement for revalidation for practice. This framework involves pharmacists keeping a CPD portfolio and submitting a record for assessment once every three to five years. Roll-out of a voluntary system of CPD will commence in autumn 2002 with 5000 pharmacists, followed by a further 10,000 in 2003 and 15,000 in 2004.

National centres for continuing education are funded to provide CPD programmes for community and primary care pharmacists. There is some national variation in the provision for hospital pharmacists and pre-registration trainees.

2.3.3 *Postgraduate training*

There is significant commitment to postgraduate clinical and therapeutic training in all sectors of pharmacy practice. During the past decade, there have been approximately one thousand pharmacists at any one time undertaking postgraduate, part-time courses at UK Schools of Pharmacy, mainly on clinical Diploma or Masters programmes. A conservative estimate indicates that there are, upon successful completion, about 400 to 500 new clinical Diploma/Masters awarded each year.

- 2.3.4 Community pharmacists who provide certain special services, such as advisory services to residential and nursing homes, are required to complete certificated training programmes. Similar requirements are being adopted for pharmacists wishing to participate in patient group directions within a Primary Care Organisation.

Hospital pharmacists who provide certain special services (cytotoxics services, anticoagulant clinics, palliative care) are also required to undertake relevant specialist training.

2.4 Regulation, registration, standards

- 2.4.1 The Royal Pharmaceutical Society of Great Britain has a unique span of authority covering professional regulation - registration, discipline, continuing professional development and assurance of competence. It maintains a Register of Pharmaceutical Chemists⁹ and an overall regulatory framework is currently being

refined, which will address fitness to practise alongside professional conduct.

The NHS Reform and Health Care Professions Bill¹⁰, for England and Wales, published in November 2001, recognises the joint regulatory and professional roles of RPSGB. The Bill limits the powers that the new overarching Council for the Regulation of Health Care Professionals (CRHP) has over the Society's activities.

2.4.2 *Registration and entry to the profession*

To become a registered pharmacist, a person must satisfy the requirements of the Society's byelaws relating to registration. Generally this means that a member is a graduate in pharmacy from a school of pharmacy approved by the Society, and has completed a suitable period of preregistration training prior to passing a registration examination. Alternative arrangements exist for registration of overseas pharmacists who wish to practise in Britain.

2.4.3 *Discipline*

Responsibility for enforcing the laws controlling the conduct of pharmacists and the sale and supply of medicines rests with the Society. Professional standards are safeguarded and maintained through the Society's disciplinary procedures. A Statutory Committee deals with breaches of the ethical code and other examples of professional misconduct. It also enforces legislation dealing with the supply of medicines to the public. The Statutory Committee has the power to direct the removal of a pharmacist or pharmacy premises from the statutory register.

2.4.4 *Code of Ethics, Standards and Service Specifications*

The public's trust in the pharmaceutical profession requires pharmacists to ensure and maintain, throughout their career, high standards of professional conduct and performance, up-to-date knowledge, and continuing competence in their sphere of practice. The Society's Code of Ethics and Standards¹¹ identifies the key responsibilities and standards of professional performance. The section on Practice Guidance includes service specifications.

3. Supplementary prescribing

3.1 The Department of Health and the Medicines Control Agency published a consultation document about the introduction of supplementary prescribing by nurses and pharmacists on April 16th 2002³. (Appendix 2) It sets out proposals for amendments to the Prescription Only Medicines (Human Use) Order 1997 (the POM Order). We welcome the general proposals set out in this document and the expectation of rapid progress in implementation. We wish to make constructive comments and proposals that will help to ensure that the changes meet the main objective of improved patient care, as well as achieving better use of pharmacists' skills.

In this section of the report we set out general observations about the role of pharmacists as supplementary prescribers in paragraphs 3.2 to 3.7 and comments on specific points raised in the consultation document in paragraph 3.8.

3.2 Definition

3.2.1 The Review of Prescribing, Supply and Administration of Medicines¹ defined the dependent (supplementary) prescriber as one 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.'

3.2.2 The Department of Health and Medicines Control Agency consultation document³ builds on the above definition and defines supplementary prescribing as:

'a voluntary prescribing partnership between the responsible independent prescriber and a supplementary prescriber, to implement an agreed patient specific clinical management plan with the patient's agreement, particularly but not only in relation to prescribing for a specific non-acute medical condition or health need affecting the patient.'

Both definitions embrace the concept of individual clinical management plans which it is expected would be based on nationally accepted clinical guidelines. The later definition also refers explicitly to prescribing partnerships, but omits reference to continuing established treatments.

We propose the following definition of supplementary prescribing:

'A voluntary partnership between the independent prescriber and a supplementary prescriber, to implement an agreed patient-specific clinical management plan with the patient's agreement.'

We think that this concise definition provides a clear description of the essential characteristics of supplementary prescribing. The word 'responsible', describing the independent prescriber in the consultation document's definition, is not necessary in the context of a professional partnership in which both participants accept responsibility for patient care. We do not believe that the definition needs to include the possible clinical situations suitable for supplementary prescribing, as this could imply that other appropriate service developments should be excluded.

3.3 Pharmacists as supplementary prescribers

3.3.1 *The benefits of supplementary prescribing by pharmacists*

The RPSGB considers that pharmacists who are supplementary prescribers will contribute to improved clinical outcomes, greater patient convenience, and the achievement of National Service Framework and National Plan guidelines.

Patients will benefit from:

- improved access to a healthcare practitioner who can provide advice, information about medicines, appropriate referrals and medicine supplies
- greater flexibility, choice and convenience
- speedier discharge from hospital by the elimination of delays in providing supplies of post-discharge medicines and advice on their use
- medicines managed to eliminate duplication, confusion and to improve understanding at discharge from hospital
- enhanced concordance with agreed clinical management plans.

The healthcare system will benefit from:

- additional professional involvement
- reduced patient waiting times in hospital and primary care
- better services for vulnerable groups
- economic gains through waste reduction.

Pharmacists will benefit from:

- enhanced professional fulfilment and job satisfaction
- the ability to put their skills to better use by more appropriate participation in the wider healthcare team
- introduction of wider continuing education programmes and competency based assessments.

3.3.2 *Conditions which could be managed by pharmacist supplementary prescribers*

A specific list of conditions is not recommended. It is likely that conditions where standards of care have been agreed would be included, such as asthma, diabetes, coronary heart disease and hypertension in primary care settings. In hospital, possible areas are hyperlipidaemia, anticoagulant therapy, pre-operative assessment and pain management.

3.3.3 *Which pharmacists should become supplementary prescribers?*

In principle, all existing pharmacists should be eligible to train as supplementary prescribers. However at the outset there will be limited training capacity so access to training will have to be decided according to the priorities of the service. Training is likely to be commissioned by the NHS through primary care organisations, hospital trusts and workforce confederations. In due course prescribing should be included in all undergraduate pharmacy programmes.

3.3.4 *What competencies are needed for supplementary prescribing?*

It is envisaged that a supplementary prescriber will be able to vary the dosage, frequency or formulation of a medicine, or to prescribe a different drug to the patient, as appropriate to the patient's condition and within the limits of an identified clinical management plan. The competencies needed by pharmacists will depend on the focus of the supplementary prescribing.

In order to fulfil these roles, the professionals concerned will have to demonstrate that they have the necessary clinical knowledge and skills. These include:

Clinical assessment and diagnostic skills

- assessment of the patient's condition
- identification of clinical changes that require alterations to the medication regime
- monitoring of responses to therapy that may require alterations to the medication regime
- identification of changes that require referral to or review by the assessing clinician
- ability to communicate effectively with both the patient and the independent prescriber.

Professional competencies

- critical appraisal skills to inform and develop evidence based practice
- familiarity with models of consultation
- understanding of legal issues related to prescribing
- understanding of ethical issues related to prescribing
- understanding of public health issues related to prescribing
- understanding of professional accountability and responsibility.

Pharmaceutical skills

Pharmacists' baseline competencies in:

- pharmacology
- pharmacokinetics
- pharmacodynamics
- drug interactions
- adverse effects of drug therapy, dosage and contraindications to specific treatments.

General therapeutic training includes the choice of therapy, taking account of its safety in relation to underlying and concomitant pathology and specific biochemical, haematological and bacteriological circumstances.

A number of postgraduate clinical pharmacy courses¹² currently offer some, or all, of the required curriculum.

Communication skills and patient empowerment

Pharmacists are well placed to act for the benefit of patients in matters relating to compliance and concordance. They can identify medication related problems. Their expertise in these areas, which is recognised by the public, and their accessibility, enhance their ability to assess and facilitate concordance.

3.4 The National Prescribing Centre

The National Prescribing Centre has published a document, 'Maintaining Competency in Prescribing'¹³ as a framework for continuing education for existing nurse prescribers. About 70% of the competencies are 'core' and relevant for prescribers of all professional backgrounds. The Task Group considers this to be an excellent document and is pleased that the Department of Health has commissioned the National Prescribing Centre to help develop a competency framework for pharmacist prescribers, to include:

- definition of the necessary competencies for pharmacist supplementary prescribers
- issues about how supplementary prescribing will work in practice e.g. development of a clinical management plan, working in teams, communication between prescribers.
- what, if any, training independent prescribers may need to enter into a supplementary prescribing partnership.

3.5 Access to Information; sharing information

3.5.1 The voluntary prescribing partnership envisaged by the Department of Health must have as a prerequisite an agreement on access to records and clear arrangements for sharing information. Good communications are seen as paramount.

3.5.2 Accurate and timely transfer of information between independent prescribers, supplementary prescribers and the patient is essential for

patient safety. Pharmacists prescribing medication will require access to the patient's medical record both to retrieve and to insert information. Hospital pharmacists are familiar with existing patient records, use them regularly and have full access. Different mechanisms will be required in the community to enable safe supplementary prescribing by community pharmacists. Referral mechanisms to other health professionals will be needed similar to those that exist now for hospital and community doctors. To maintain full patient choice 'pull down' electronic access or a patient held 'smart' card will be required.

3.5.3 The Department of Health's endpoint for electronic prescribing and free transfer of information appears to be several years away. In the interim, serious consideration should be given to the introduction of patient held records relevant to primary and secondary sector care. These should be available throughout the NHS for those patients who wish to participate.

3.5.4 We welcome the Department of Health's commitment to achieve extended access to the NHSnet to include all pharmacists by 2004 and the steps that have been taken by the Scottish NHS Executive in some parts of Scotland.

3.6 Confidentiality

Greater sharing of patient information has implications for confidentiality and patient consent. There is potential for conflict between 'sharing information' and 'preserving confidentiality'. Uncertainty amongst professionals about the legal and ethical aspects of sharing patient information, which is important for teamworking, can create barriers.

Local 'Caldicott Guardians' are required to safeguard confidential patient information. Guidance from the Confidentiality and Security Advisory Body should assist all NHS bodies and health professionals in dealing with these matters.

3.7 Organisational issues

3.7.1 The organisational arrangements for supplementary prescribing must be designed to protect patient safety. For pharmacists, working within an agreed clinical management plan, this requires clear arrangements to ensure the maintenance of professional standards, that are auditable and open to external scrutiny, and are respected by other professionals and the public.

3.7.2 The introduction of clinical governance within the NHS provides a possible framework for such arrangements. All pharmacist supplementary prescribers must participate in a recognised clinical governance programme that is designed to meet their specific needs.

3.7.3 We recommend that the Society develop national standards for such programmes. They should include clear statements of the requirements for:

- the data and information needed
- risk management
- audit
- rapid identification and response to problems
- regular monitoring and review.

These arrangements will be needed for the support of pharmacists working in all practice settings.

3.7.4 The Society should also set standards to uphold the probity of the profession in circumstances where the supplementary prescriber has a direct financial interest in the service provision arrangements, for example in the duration of prescriptions and frequency of repeat prescriptions.

3.7.5 We believe that such arrangements, properly regulated by the Society, will establish safe systems that will meet all the concerns of those who are worried that changes in the traditional separation of the prescribing and supply of medicines will diminish the safeguards for patients.

3.8 Specific comments on consultation document MLX 284

The Task Group strongly welcomes the consultation document and the commitment of Ministers to the implementation of supplementary prescribing by nurses and pharmacists. The pace of implementation is likely to be rapid, but we are convinced that pharmacists and their professional colleagues will make great efforts to ensure that training programmes and administrative systems will be ready in good time. The lessons already learned from the introduction of nurse prescribing will be of great assistance in this.

The following comments relate to specific points in the consultation document, which is attached at Appendix 2 for ease of reference to the relevant paragraphs.

i. Para 4.

We support the introduction of supplementary prescribing outside the NHS but recommend that it is made clear that patients treated outside the NHS in private practice may not be issued with NHS prescriptions, in line with the arrangements for existing prescribers working outside the NHS.

ii. Para 8.

Definition: (see para 3.2 of this report) the group favours the following concise definition of supplementary prescribing:

“A voluntary partnership between the independent prescriber and a supplementary prescriber, to implement an agreed

patient-specific clinical management plan with the patient's agreement."

We think that this provides a clear description of the essential characteristics of supplementary prescribing. The word 'responsible', describing the independent prescriber in the consultation document's definition is not necessary in the context of a professional partnership in which both participants accept responsibility for patient care. We do not think that the definition needs to include the possible clinical situations suitable for supplementary prescribing, as this could imply that other appropriate service developments should be excluded.

iii. Para 9.

We propose that all registered pharmacists should be considered potential supplementary prescribers and that the priority for public funding of prescribing training should be determined by the needs of patients and the clinical services. In the future we think that training for prescribing should be incorporated into the undergraduate curriculum, with registration as a prescriber being achieved after successful completion of a period of competency based supervised practice.

iv. Para 10.

We endorse the first six principles of supplementary prescribing set out in Paragraph 10, but we disagree with the seventh (final) principle.

We consider that the separation of the prescribing and supply of medicines is no longer necessary to maintain patient safety and good governance (see para 3.7 of this report). We expect all pharmacist prescribers to participate in an approved programme of clinical governance, which establishes sound systems for patient safety. This may, when necessary, include the requirement for a second technical check at the time of supply of a medicine, to confirm accurate assembly and labelling, but such a check does not have to be carried out by a registered pharmacist. Concerns about other aspects of governance are met by the presence of adequate audit arrangements.

We suggest that the point on access to records should be clarified to state that 'all prescribers must have access to the patient's clinical and medication records'. We recognise that there may be rare instances when it might be justified for some parts of the medical record to remain confidential to the independent prescriber. However, we consider that all health professionals who are responsible enough to be registered prescribers should be assumed to understand fully the requirements for confidentiality.

We also consider that the regulatory bodies will be able to deal appropriately with any instances of professional misconduct. The use of patient-held records would ensure that the patient consented to the transfer of information between prescribers. It is important that the introduction of supplementary prescribing extends, rather than diminishes, patient choice and that patients who do not

wish information about their medical state to be accessible to supplementary prescribers understand that they can remain under the sole care of the independent prescriber.

v. Para 11.

We endorse the criteria for lawful supplementary prescribing, but think that there should be a clear definition of a 'clinical management plan'. For example, is a hospital medical record a clinical management plan, or would a separately identified section in the record be required? A large number of patients cross the interface between hospital and primary care. We think that supplementary prescribing in hospital practice will only be realistic if the clinical management plan is derived from the clinical team's work and the in-patient prescribing chart, modified at discharge to take account of hospital and directorate agreed guidelines.

We are also concerned that rigid and complex requirements for a primary care based clinical management plan might deter practitioners from grasping the new opportunities to extend services.

We consider the best approach would be for the Department of Health to invite a group of doctors, nurses and pharmacists to develop criteria for a clinical management plan.

vi. Para 13.

We heartily welcome the proposal not to restrict the range of medicines to which supplementary prescribers will have access. Any limitations would reduce the usefulness of this service development for patients and the benefits to the NHS. We hope that arrangements for the inclusion of controlled drugs will soon be agreed so that the range of care suitable for supplementary prescribing can be extended to include patients who need expert pain control.

vii. Para 14.

We think there should be flexibility in the inclusion of medicines used outside their licensed indications. We agree that it is essential in paediatric practice. We think that the use of off-licence medicines should also be allowed if it is agreed by both prescribers.

viii Para 16.

We agree that products that are "less suitable for prescribing" should be included if agreed by both prescribers.

ix. Paras 18 and 19.

We agree in large with these paragraphs, but think there should be clearer guidance about the definition of a 'clinical management plan' in hospital practice (see para v). In addition we recommend that there should be more detailed guidance on the criteria for the plan, for instance that it should be evidence based and consistent with recognised clinical guidelines. It should be agreed by prescribers and the patient and, where appropriate, the carer or parent, and there should be explicit arrangements systematic review.

x. Paras 20-22.

We think that the proposal that supplementary prescribing is based on a partnership between two individual practitioners is unrealistic if it is to offer full time care. The problems relate not only to the independent prescriber but also to the pharmacist or nurse supplementary prescriber who will not always be immediately available to provide services.

In hospital practice, we think that the independent prescribers should be a specified medical team, with responsibility in the hands of the consultant head of that team or a nominated deputy. The supplementary prescribers should be identified pharmacists with training and experience appropriate to the clinical area concerned, nominated by the hospital Chief Pharmacist. In community practice the independent prescribers should be a group of general practitioners agreed by the practice and/or the Primary Care Trust. The supplementary prescribers should be nominated pharmacists approved by the pharmacy advisor of the primary care organisation.

These proposals appear to us to be consistent with other recent Government policy initiatives such as the proposed new general practitioner contract. In all cases the individual patient must agree to the arrangements. We recognise that these ideas introduce complexity into the system, but fear that undue simplicity will not achieve the stated aims and could lead to a return of the practices we are trying to eliminate, such as signed blank prescriptions.

xi. Paras 23 and 24.

We agree with the summary of responsibilities of independent and supplementary prescribers, though we see the partnership as mutually supportive, not just the independent prescriber supporting the supplementary prescriber colleague.

xii. Paras 25-27.

We think that the same core training will be needed for independent and supplementary prescribing and that the introduction of extended prescribing offers exciting opportunities for multidisciplinary education and training in the core modules.

We expect that the training and continuing education of independent prescribers will in future match that being developed for new prescribers and that courses will be shared where possible. We also suggest that training for prescribing partnerships should involve all participants, not just the independent prescribers.

xiii. Para 30.

Our comments on the specific proposals identified in the consultation document are as follows:

- We strongly support proposals to amend the POM Order to enable supplementary prescribers to prescribe prescription only medicines as part of an agreed clinical management plan for an individual patient.
- We recommend an amended definition of supplementary prescribing. (see 3.2.2 of this report, plus point ii above)
- We endorse six of the principles of supplementary prescribing set out in para 10, but disagree with the principle relating to the separation of prescribing and supply of medicines. (see point iv.) We also recommend clarification and strengthening of the statement on access to records. (3.5.1 and point iv)
- We support the proposed legislative requirements set out in para 11 but think it is essential to provide a clear definition of 'clinical management plan' for hospital and for community based services. (points v and ix above)
- We strongly support the proposal that no legal restrictions should be placed on the range of medicines (with the exception of controlled drugs and unlicensed medicines outside paediatric care) or clinical conditions for supplementary prescribing. We think that any such limitations would significantly reduce the contributions of supplementary prescribing to improved patient care. We hope that controlled drugs will be included as soon as possible. We also suggest that medicines being used 'off-licence' can be included. (points vi and vii)
- We endorse the proposals for the clinical management plan subject to the inclusion of a clear definition of such a plan (point v) and more detailed guidance on the criteria for a clinical management plan. (point ix).
- We think that restriction of supplementary prescribing to partnerships of one named independent prescriber and one named supplementary prescriber is incompatible with continuing patient care and would severely limit the usefulness of supplementary prescribing to patients, professionals and the health service. The prescribing partnership must recognise that patient care is largely delivered by teams, in both hospital and community-based practice. (point x)
- We envisage that the professional partnership between independent and supplementary prescribers will be mutually supportive and that training for this role will be undertaken jointly. (points xi and xii)

4. Education and Training

In considering the implications of prescribing for education and training, the task group believes the role of the professional body, RPSGB, is to set standards for pharmacists' education and competence and to accredit and register pharmacists. The Society is not itself a training organisation.

4.1 In giving consideration to the education and training needs for pharmacists who will prescribe, we have made a number of assumptions. First, that pharmacists will ultimately, and in all probability within a few years, undertake independent as well as supplementary prescribing. Second, that in response to that extension to the scope of practice of pharmacists, the undergraduate course and pre-registration programme will incorporate the necessary additional knowledge and skills required.

4.2 This leads us to believe that the necessary additional educational and training should be considered in three phases:

i. Modifications and additions to the M.Pharm. degree and pre-registration year. These changes would be designed to equip future pharmacists to prescribe following their standard training. Ultimately, this will lead to all pharmacists having the same level of ability to prescribe and a universal standard of prescribing practice. The time frame and resource consequences of this require early consideration to allow for necessary curriculum development to be undertaken by the Schools of Pharmacy. Since this aspect is beyond the remit of this report we will not develop our proposals further but we are aware that the issue is being taken forward by the Education Committee of the RPSGB. It is noted, however, that there is a degree of variation amongst Schools of Pharmacy in their timing of implementation of changes. There is also a view that the fourth year of M.Pharm courses should include more interactive professional practice than at present.

ii. Top up training for people currently studying for the M.Pharm. Degree or in their pre-registration year. We believe that this group could rapidly undertake the additional training necessary and acquire supplementary knowledge in respect of clinical pharmacology and other aspects of prescribing practice not currently within the curriculum. This 'top up' training, which will include appropriate and adequate clinical training and also training in the legal, ethical, and teamwork aspects of prescribing practice, may also be suitable for recently qualified pharmacists. An element of supervised practice will be required, together with training for the supervisory role. Particular thought needs to be given to arrangements for supervised practice in community settings.

iii. A comprehensive programme of preparation for longer serving pharmacists. This will give longer serving pharmacists an opportunity to revise, update and extend their knowledge of pathophysiology and

pharmacology. It will be based on the generic competencies identified as necessary for good prescribing practice and will be assessed to ensure that the required competencies have been acquired.

4.3 The task group acknowledges the concept of accrediting prior learning but places emphasis on the importance of competency testing. Operational issues will need to be developed, including:

- who will undertake the testing of pharmacists' prescribing competencies?
- how will these activities be organised?
- who will fund the testing?
- how will standardisation throughout the UK be achieved?

Preparation of the additional training curriculum

4.4 We recommend that the Royal Pharmaceutical Society of Great Britain, working with the Department of Health, Schools of Pharmacy and the universities be asked to draw up appropriate course and programme specifications to meet the needs of each of these groups. In doing so we would expect the design to be flexible so as to avoid duplication of effort. We also recommend that, in those locations where it is feasible, the appropriate sections or modules are taken on a multi-professional basis with other prescribing health professions.

4.5 A balance needs to be struck between the earlier training for supplementary prescribing and the anticipated later requirements of independent prescribing. It is possible that a course designed in two components would provide for transition in a similar way to that adopted for nurse prescribing. Alternatively the view might be taken that a single, comprehensive pathway encompassing the full range of knowledge and skills would prove more efficient. Existing courses in clinical pharmacy may provide a useful model for developing clinical aspects of the new programme with suitable opportunities for progression.

4.6 The National Prescribing Centre has developed a clear set of competencies, some of which are applicable to all prescribing health professions. The Department of Health has commissioned the NPC to develop a competence framework for pharmacists based on the current nurse prescribing competence framework (described in section 3.4).

4.7 A multi-disciplinary group including representatives from Scotland, Wales and Northern Ireland has been set up by the Chief Pharmaceutical Officer, Department of Health. The group will consider arrangements for ensuring that pharmacists have the necessary knowledge, skills and expertise to be competent supplementary prescribers. It will review:

- curriculum requirements
- assessment criteria and strategies
- commissioning and funding of training
- arrangements of professional registration
- continuing professional development.

4.8 It is expected that the RPSGB and Department will work in collaboration in developing the education and training requirements for pharmacist supplementary prescribers. The RPSGB will retain responsibility for the accreditation and registration of pharmacists (see section 5, Regulation and registration). The final education and training programme will have to be refined in light of the outcome of the current consultation.

4.9 Once training is completed, the task group recommends that criteria be established for the demonstration of continuing competence and the maintenance of high standards of practice as part of the normal continuing professional development for prescribing pharmacists.

Modes of Delivery

4.10 We believe that additional training to facilitate prescribing should be both flexible and easily accessible. To that end we recommend that the Royal Pharmaceutical Society should work with the national Centres for Postgraduate Pharmacy Education as well as the Schools of Pharmacy and universities, to develop novel approaches to this large scale CPD exercise.

4.11 Some aspects of the programme will necessarily involve attendance at appropriate centres and access to clinical facilities for practice based work. As much of the programme as possible should be accessed on line and by other distance and open learning methods. This will allow the greatest number of pharmacists to participate, irrespective of the location of their practice. However, interaction with patients and other professionals is seen as a key component. Learning from meeting with peers is very valuable both in terms of learning from each other and in developing a support network.

4.12 Clinical aspects of the programme will require the participation of experienced clinical pharmacists and medical and nursing practitioners. This will have resource implications.

Resource Implications of Additional Training

4.13 Curriculum development to design and implement an appropriate programme, the need to provide suitable clinical support and professional input and the time required from participating pharmacists will each require adequate resources.

4.14 We recommend that the Workforce Development Confederations of the NHS (in relation to training for pharmacists) and the Higher Education Funding Councils (for pharmacy undergraduates) be requested to consider these implications and provide the necessary funding support. The value to be added to health care has been summarised in section 3 of the report. We believe that the advantages to be gained from a highly trained and skilled pharmacist workforce, with the ability to prescribe, are compelling. The value added, achieved through pharmacist prescribing, is likely to be significant and justifies prioritisation for investment of part of the Multiprofessional Education and Training budget (MPET) administered by the Workforce Development

Confederations. Similarly, the additional clinical components, implicit for the undergraduate curriculum, should be appropriately recognised and funded by the Higher Education Funding Councils (HEFCs).

5. Regulation and registration

5.1 Professional regulation and the systems to ensure competence including education, registration, training, continuing professional development and future revalidation are recognised as being the responsibility of the RPSGB. Pharmacist prescribers or supplementary prescribers will need to be readily identifiable and the register of pharmacists should be the core source to which pharmacist's prescribing status is linked.

5.2 The RPSGB's electronic database has the capacity to link and annotate individuals in a variety of ways. In the medium term, as with other regulators, it is envisaged that registration records will be electronically accessible and continually updated. However, in the short term we recommend that, alongside database development, the RPSGB explore how best to annotate or allow for separate indication of a pharmacist's prescribing status in the printed register. Given that the current form of the register is specified in a schedule to the byelaws an appropriate byelaw change should be drafted.

6. Recommendations

These recommendations are intended to assist the Society in developing plans for the introduction of supplementary prescribing by pharmacists, and to help prepare for independent prescribing.

We recommend:

To the Department of Health

1. The definition of supplementary prescribing be amended to read:
'A voluntary partnership between the independent prescriber and a supplementary prescriber, to implement an agreed patient-specific clinical management plan with the patient's agreement.' (3.2.2)
2. In principle, all registered pharmacists should be eligible to train as supplementary prescribers, but acknowledge at the outset that there will be limited training capacity. The priority for public funding of prescribing training should be determined by the needs of patients and clinical services. (3.3.3)
3. The prescribing partnership must have as a prerequisite an agreement on access to records and clear arrangements for sharing information. (3.5.1)
4. Serious consideration should be given to the introduction of patient held records, available throughout the NHS for those patients who wish to participate. (3.5.3)
5. There should be a clear definition of a 'clinical management plan' and more detailed guidance on the criteria for the plan. (3.8.v)

To the RPSGB

6. The RPSGB should develop national standards for clinical governance programmes designed to meet the specific needs of all supplementary prescribers. (3.7.3, 3.7.4, 3.7.5)
7. The RPSGB, working with the Department of Health, Schools of Pharmacy and the universities should be asked to draw up appropriate course and programme specifications to meet the needs of pharmacists and pharmacy undergraduates. (4.4)
8. The RPSGB should work with the Department of Health to enable the timely development of a competency framework for pharmacist supplementary prescribing. (3.4, 4.6, 4.7, 4.8)

9. The RPSGB, with educational establishments, should develop criteria for the demonstration of ongoing competence as part of CPD for prescribing pharmacists. (4.9)

10. The RPSGB should work with the national Centres for Postgraduate Pharmacy Education as well as the Schools of Pharmacy and universities, to develop novel approaches to CPD for prescribing pharmacists. (4.10)

11. The RPSGB should consider drafting an appropriate byelaw to allow a separate indication or annotation of the Register of Pharmaceutical Chemists to record the prescribing status of registered pharmacists. (5.2)

To the NHS and Higher Educational Funding Councils

12. The Workforce Development Confederations of the NHS (in relation to training for pharmacists) and the Higher Education Funding Councils (for pharmacy undergraduates) be requested to consider resource implications for the education and training requirements, and provide the necessary funding support. (4.13, 4.14)

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Appendix 1

PHARMACIST PRESCRIBING TASK GROUP

Membership: Dr June Crown, Chairman

Mr Peter Curphey, community pharmacist; RPSGB Council

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Mr Anthony West	Guild of Healthcare Pharmacists
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Ms Maureen Williams	UKCC
Dr Peter Wilson	CPPE

Note: Wider Consultative Group meetings also attended by members of the Pharmacist Prescribing Task Group

Appendix 2

Tel: 020 7273 0642
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To: Interested Organisations
MLX 284

Our reference:

Date: 16 April 2002

Dear Sir/Madam

PROPOSALS FOR SUPPLEMENTARY PRESCRIBING BY NURSES AND PHARMACISTS AND PROPOSED AMENDMENTS TO THE PRESCRIPTION ONLY MEDICINES (HUMAN USE) ORDER 1997

INTRODUCTION

1. In accordance with section 129(6) of the Medicines Act 1968, I am writing to consult you on proposals to amend the Prescription Only Medicines (Human Use) Order 1997 (the POM Order) so as to provide that prescription only medicines may be prescribed by a "supplementary prescriber" (see paragraph 5 below) as part of an agreed clinical management plan for an individual patient. This letter also seeks views on the wider proposals for supplementary prescribing. In addition to prescription only medicines, it is proposed that supplementary prescribers should also be able to prescribe all pharmacy (with the exception of those P products which are schedule 5 controlled drugs (see paragraph 16)) and general sale list (GSL) medicines, appliances and devices, foods and other borderline substances, in accordance with the clinical management plan, which are prescribable by independent prescribers (that is, doctors or dentists) under the NHS.
2. The proposals are intended to enhance patient care by providing quicker and more efficient access to healthcare through an increased and flexible use of nurses' and pharmacists' skills. This consultation letter has been produced jointly by the Medicines Control Agency and the Department of Health, following informal consultation meetings between the Department and representatives of the medical, nursing and pharmacy professions between November and February 2002. These meetings helped develop a number of proposed principles on which supplementary prescribing should be founded. Those principles are covered in greater detail in this letter.

Application to the NHS in England, Wales, Scotland and Northern Ireland

3. The proposed changes to the POM Order would permit prescription only medicines to be prescribed by a supplementary prescriber, as part of an agreed clinical management plan for an individual patient, throughout the United Kingdom. This consultation is also being circulated in Wales, Scotland and Northern Ireland. However, the extent to which Supplementary Prescribing is adopted within the NHS in devolved administrations is a matter for each of the separate administrations. In due course, the Department of Health intends to produce additional guidance to help implement the proposed legislative changes.

Application outside the NHS in England, Wales, Scotland and Northern Ireland

4. The proposed changes to the POM Order would also apply to organisations providing healthcare outside the National Health Service.¹ Supplementary Prescribing arrangements introduced by such organisations would have to comply with the legislative requirements and they should also consider developing accompanying guidance.

BACKGROUND

5. In the report on the Review of Prescribing, Supply and Administration of Medicines² the act of prescribing a medicine is described as 'part of a process which starts with the overall clinical assessment of an individual who presents for preventive care or treatment'. The Review Team suggested that, following clinical assessment, and 'once a diagnosis has been established or a treatment plan prepared', responsibility for clinical management of the individual, including prescribing, could pass to another health professional. The Review refers to this second prescriber as a 'dependent prescriber': the preferred term is now 'supplementary prescriber' and that is the term used throughout this letter. The proposed roles and responsibilities of both independent and supplementary prescribers are set out in paragraphs 23 and 24 below.
6. The proposals in this letter are complementary to the more recent proposals to extend the range of POMs available to independent nurse prescribers who have undertaken preparation and training to prescribe from an extended formulary of medicines.
7. Ministers have decided that supplementary prescribing will be introduced initially for nurses and pharmacists, and that extending this to other healthcare professions will be considered in the light of this experience.

¹ As defined in the Care Standards Act 2000

² The report on the Review of Prescribing, Supply and Administration of Medicines, prepared under the Chairmanship of Dr June Crown, was published in March 1999 and is available on the Department of Health Website - www.doh.gov.uk/prescrib.htm

We would however welcome views from other professions on the applicability of these proposals to those healthcare professions.

PROPOSALS

Supplementary Prescribing – Proposed Working Definition

8. Informal meetings with a number of representative bodies (a list of those consulted is at Annex A) has helped to refine the following proposed working definition of supplementary prescribing:

“ A voluntary partnership between the responsible independent prescriber and a supplementary prescriber, to implement an agreed patient-specific clinical management plan with the patient’s agreement, particularly but not only in relation to prescribing for a specific non-acute medical condition or health need affecting the patient.”

This definition provides a description of the proposed relationship between the supplementary and independent prescriber but the precise legislative provisions will need to be considered in more detail outside this consultation.

9. The prerequisites for supplementary prescribing would therefore be a partnership between the independent and the supplementary prescriber and a written individual clinical management plan for the patient’s condition. For the foreseeable future, and for the purpose of this consultation, the independent prescriber will be a doctor or dentist (i.e. independent nurse prescribers are not included, though they will be able to become supplementary prescribers). For the purpose of this consultation, supplementary prescribers would be nurses or pharmacists. Training and accreditation for nurses and pharmacists who may undertake supplementary prescribing will be planned in conjunction with appropriate professional organisations. In the light of experience gained from independent nurse prescribing and associated training, timescales for nurses and pharmacists may differ. It is not expected that all nurses or all pharmacists will undertake the preparation for, or the role of, supplementary prescriber. Supplementary prescribing should only take place where there is worthwhile benefit to patients and the NHS (or, outside the NHS, to patients and the independent healthcare sector) through using the skills of nurses and pharmacists more flexibly.

Proposed Principles of supplementary prescribing

10. The proposed principles of supplementary prescribing are that:
- patient safety should be paramount
 - the patient (or where appropriate their carer or parent) agrees to the arrangement
 - there should be benefit to patients and the NHS
 - good communication between all prescribers and access to the patient's record is essential
 - supplementary prescribing should support but not replace multi-disciplinary care
 - both the independent and the supplementary prescriber will need preparation before entering a prescribing partnership
 - prescribing and dispensing responsibilities should, where possible, be separate in keeping with the principles of patient safety and governance.

Criteria for lawful Supplementary Prescribing

11. We propose to specify, in an amendment to the POM Order, the conditions which must be met if supplementary prescribing is to take place. The proposed particulars are:
- the independent prescriber must be a doctor or dentist, as appropriate
 - the supplementary prescriber must be a Registered Nurse, (including Registered Health Visitor), Registered Midwife or a registered pharmacist
 - there must be a written clinical management plan relating to a named patient and to that patient's specific condition, and that plan must be agreed and signed by both the independent and supplementary prescribers
 - the clinical management plan must specify the range of medicines that may be prescribed for the named patient by the supplementary prescriber, also-specify the range and circumstances within which the supplementary prescriber can vary the dosage, frequency and formulation of the specified range of medicines as appropriate, and when to refer back to the independent prescriber
 - the clinical management plan must contain relevant warnings about any known sensitivities of the patient to particular medicines and include arrangements for the notification of any adverse drug reactions. (See also paragraphs 15 and 24)
 - the clinical management plan must contain the date on which the Supplementary Prescribing arrangements commence and the date

on which the arrangements should be reviewed, which should normally not be longer than one year.

- both independent and supplementary prescribers must share access to, consult and use the same common patient record.

Clinical Conditions most benefiting from Supplementary Prescribing

12. Supplementary Prescribing will be of most value to patients with specific non-acute medical conditions (e.g. asthma, diabetes, and conditions related to mental health), or health needs (e.g. anticoagulation treatment, HRT, or prophylaxis against coronary heart disease). It is not, however, proposed to restrict Supplementary Prescribing to specific clinical conditions – the decision to introduce Supplementary Prescribing arrangements for a specific patient will depend on agreement between the independent and the supplementary prescriber, and the patient, to implement an agreed clinical management plan for that patient's condition.

Medicines to be included in Supplementary Prescribing

13. It is not proposed to restrict the range of medicines (with the exception of controlled drugs and unlicensed medicines outside paediatric care paragraphs 14 and 17) that can be prescribed under Supplementary Prescribing. Normally, the use of medicines should be consistent with the Summary of Product Characteristics (SPC) for the relevant product.
14. We have considered whether unlicensed medicines should be excluded from Supplementary Prescribing. We have provisionally concluded that they should be, with the exception of paediatric care. The independent and supplementary prescriber would need to agree that the use of unlicensed medicines in paediatric care is appropriate and justified by best practice. We would particularly welcome views on this. We have also provisionally concluded that to exclude the prescribing of a product for use outside its licensed indications, again where the independent and supplementary prescriber agree that it is appropriate and justified by best practice, would be unnecessarily restrictive. The clinical management plan should clearly state when an unlicensed product is being used or when a product is being used outside the terms of the SPC. We would welcome views on these proposals.
15. Similar consideration has been given to the exclusion of black triangle drugs (i.e., those products recently licensed and subject to special reporting arrangements for adverse reactions). We have provisionally concluded that to exclude such use, where the independent and supplementary prescriber agree that it is appropriate, would be unnecessarily restrictive. Pharmacists currently report adverse drug reactions (ADRs) on their own authority. Following the evaluation of pilot schemes of ADR reporting by nurses, the MCA/CSM are currently developing a strategy for the introduction of nurse reporting. The first step

is the development of educational and training programmes to include information on adverse drug reactions. Commencement of nurse reporting will be communicated widely when the initiative is launched. Until that time nurses should report all ADRs, not only those arising from the black triangle drugs, to the independent prescriber. We would welcome views on these proposals.

16. It is also proposed that those products currently suggested by the British National Formulary to be "less suitable for prescribing" may be included in Supplementary Prescribing, where the independent and supplementary prescriber agree that such use is appropriate for the patient. We would welcome views on this proposal.
17. The prescribing of controlled drugs is subject to the Misuse of Drugs Act 1971 and Regulations made under that Act. The Regulations permit a doctor or dentist to prescribe controlled drugs, but these provisions do not at present cover prescription by other health professionals. The inclusion of controlled drugs in Supplementary Prescribing would necessitate changes to be made to the misuse of drugs legislation. This would require consideration by the Home Office, who would need to seek the advice of the Advisory Council on the Misuse of Drugs. Until that is possible, controlled drugs are to be excluded from the scope of Supplementary Prescribing.

The Clinical Management Plan

18. In addition to the legal requirements for the clinical management plan (paragraph 11), drawn up in conjunction with the supplementary prescriber, the prescribers should ideally discuss and agree that plan in conjunction with the patient. In defining the limits of prescribing by the supplementary prescriber, the clinical management plan may include reference to recognised and authoritative clinical guidelines and guidance, whether written or electronic.
19. The independent and supplementary prescribers will maintain communication on a regular basis as appropriate to the patient's condition, while the supplementary prescriber is reviewing and prescribing for the patient and monitoring the patient's progress. The independent and supplementary prescribers should ideally jointly carry out the formal clinical review at the agreed time. If a joint clinical review is not possible, the outcome of the review by the independent prescriber should be discussed jointly by both prescribers, and both prescribers should agree to the continued or revised clinical management plan. The outcome of the formal clinical review should also be discussed and agreed with the patient.

Prescribing Partnerships

20. The relationship between individual independent and supplementary

prescribers is key to safe and effective supplementary prescribing. Such a partnership will be voluntary, with both prescribers prepared to share responsibility as described below, and to be professionally accountable for their own decisions, including their prescribing decisions. The independent prescriber will be the clinician responsible for the individual's care at the time of initial assessment, or at the time that supplementary prescribing is to start. If that responsibility moves from one medical practitioner to another, the supplementary prescriber cannot continue to prescribe for that patient, unless a new partnership agreement is reached, and recorded in the patient record, with the new independent prescriber.

21. In some circumstances, most commonly in hospitals, clinics and GP practices where any one of a number of doctors may be available to treat a patient, it may be more practical to have more than one named independent prescriber rather than one individual. We would welcome views on how supplementary prescribing might work in hospitals, clinics and GP practices in relation to teams of doctors, nurses or pharmacists.

22. It is proposed that both independent and supplementary prescriber may work in more than one prescribing partnership, providing that in each case they work as proposed in this consultation letter.

23. The **independent prescriber** is responsible for:

- the initial clinical assessment of the patient and the formulation of a diagnosis,
- the development of a written clinical management plan, in conjunction with the supplementary prescriber, following diagnosis
- ensuring the clinical management plan is kept up-to-date
- informing the supplementary prescriber of the limits of responsibility delegated to that supplementary prescriber
- providing advice and support to the supplementary prescriber as required
- carrying out a review of patient's progress at appropriate intervals, depending on the nature and stability of a patient's condition, or at the request of the supplementary prescriber, and normally not longer than 1 year from the initial assessment
- resuming full responsibility for the patient's care at the request of the supplementary prescriber,
- providing access to the patient's record for the supplementary prescriber.

24. The **supplementary prescriber** is responsible for:

- monitoring and assessing the patient's progress as set out in the clinical management plan, and as appropriate to the medicines prescribed, including the reporting of any adverse reactions
- contributing to the clinical management plan

- prescribing for the patient in accordance with the agreed clinical management plan
- changing the medicine prescribed, within the limits set out in the clinical management plan, if monitoring of the patient's progress indicates that this is clinically appropriate
- working at all times within their clinical competence and their professional Code of Conduct, consulting the independent prescriber as necessary and particularly if a matter falls outside their own clinical competence.
- accepting clinical responsibility and professional accountability for their prescribing decisions and practice
- referring prescribing responsibility back to the independent prescriber if the agreed clinical reviews are not carried out within the intervals specified in the clinical management plan or if monitoring of the patient's progress indicates that this is appropriate
- as soon as possible, and preferably contemporaneously, recording clinically relevant facts, including prescribing and monitoring activity, in the patient's medical records.

Training and Preparation

25. Before starting to undertake supplementary prescribing, the nurse or pharmacist will need to:

- successfully complete the specified training and preparation for supplementary prescribing
- record their supplementary prescribing competency on the relevant professional register
- agree with their employer that supplementary prescribing should be included in their job description.
- make arrangements with their employer or the independent prescriber to obtain prescription pads or access to other appropriate prescribing arrangements (such as patients' prescription charts in hospitals), and for access to an identified prescribing budget.
- reach agreement with the independent prescriber to enter into a prescribing partnership, agree the individual clinical management plan for a patient, and record that agreement in the patient's record.

26. The training and preparation required for nurses who are to become supplementary prescribers is likely to be based on the programme of preparation and training for independent nurse prescribing. That course covers:

- consultation, decision-making, therapy and referral
- influences on and psychology of prescribing
- prescribing in a team context
- clinical pharmacology including the effects of co-morbidity and recognition of potential adverse drug reactions
- evidence-based practice and clinical governance in relation to nurse prescribing

- legal, policy and ethical aspects
- professional accountability and responsibility
- prescribing in the public health context.

With regard to nurses only, we would welcome comments on whether successful completion of this programme should enable nurses to qualify as both independent and supplementary prescribers. A similar outline has yet to be developed for pharmacists, but we anticipate that it will involve many of the same principles, though with less emphasis on some areas and more on others.

27. Independent prescribers (doctors and dentists) will also need to undertake some form of brief preparation before entering the prescribing partnership.

COMPLIANCE WITH OTHER RELEVANT LEGISLATION

28. The sale and supply of medicines under Supplementary Prescribing would have to comply with all other relevant legislative requirements relating to the supply of medicines.

REGULATORY IMPACT

29. An initial regulatory impact assessment is at Annex B.

COMMENTS

30. We plan to implement the changes during 2002 and early 2003, subject to comments received and the views of the Committee of Safety of Medicines, the Medicines Commission and Ministers. You are invited to comment on the proposals contained in this letter, particularly:

- the proposals to amend the POM Order to enable supplementary prescribers to prescribe prescription only medicines as part of an agreed clinical management plan for an individual patient.
- the proposed working definition and principles of supplementary prescribing – paragraphs 7 and 10
- the proposed legislative requirements – paragraph 11
- that no legal restrictions should be placed on the range of medicines (with the exception of controlled drugs and unlicensed medicines outside paediatric care) or clinical conditions for Supplementary Prescribing – paragraphs 12 to 17
- the scope of the clinical management plan – paragraphs 18 and 19
- the arrangements that are appropriate when services are delivered by teams of doctors, nurses or pharmacists – paragraph 21
- the proposed roles and responsibilities of independent and supplementary prescribers - paragraphs 23 and 24
- proposals for training and preparation for supplementary prescribing for nurses - paragraph 26

Comments are also invited on the regulatory impact assessment. A form at Annex C is attached for your reply. This letter and attachments will also appear on the Agency's website (www.mca.gov.uk)

31. To help informed debate on the issues raised by this consultation exercise, the Agency intends to make copies of replies received publicly available. It will be assumed that your reply can be made publicly available in this way **unless** you indicate that you wish all, or part, of it to be treated as confidential and excluded from this arrangement.
32. **Comments should be addressed to Mrs Anne Ryan, MCA, 16-142, MCA, Market Towers, 1, Nine Elms Lane, London SW8 5NQ (e-mail to anne.ryan@mca.gov.uk) and arrive no later than 9 July 2002.**

Yours faithfully

Anne Thyer
Executive Support
Medicines Control Agency

Paul Robinson
Medicines, Pharmacy and Industry Group
Department of Health

Royal Pharmaceutical Society of Great Britain

**Outline Curriculum for Training Programmes to prepare Pharmacist
Supplementary Prescribers**

Introduction and Background

This curriculum contains the specification for programmes of study to prepare pharmacists to register as supplementary prescribers. It builds on the strengths in theoretical and applied therapeutics which pharmacists acquire from their initial training and through experience in practice. From the summer of 2002, newly registered pharmacists will have been educated on a four-year degree programme to 'Master's' level. Undergraduate education and training programmes give pharmacists a strong foundation in pharmacodynamics, pharmacology, pharmacokinetics and toxicity of medicines, and how they may be used to prevent and treat illness, relieve symptoms or assist in the diagnosis of disease. This is underpinned by knowledge of the law relating to pharmacy and medicines and its application together with supervised experience of working with patients. Once qualified, many pharmacists undertake additional postgraduate clinical training at Masters level.

The level of relevant knowledge and expertise of pharmacists entering a training programme will depend on the nature of their practice and the length of their experience. The design and delivery of programmes will need to take account of the range of pharmacists' background expertise, experience and skills and will be expected to confirm their competence in prescribing through appropriate assessment strategies.

The Royal Pharmaceutical Society's Code of Ethics and Standards requires that pharmacists ensure that their knowledge, skills and performance are of a high quality, up to date, evidence based and relevant to their field of practice. Pharmacists who register as Supplementary Prescribers will need to demonstrate evidence of relevant Continuing Professional Development to ensure that their prescribing skills are kept up to date and are extended as their prescribing role develops.

ENTRY REQUIREMENTS

All entrants to this education programme must meet the following requirements:

- Current registration with RPSGB &/or PSNI
- Support from the sponsoring organisation e.g. a primary care organisation or NHS Trust, including confirmation that the entrant will have appropriate supervised practice in the clinical area in which they are expected to prescribe and that there is an identified service need for this extension of role

- Have a named medical practitioner, recognised by the employing/Health Service commissioning organization a) as having experience in a relevant field of practice, b) training and experience in the supervision, support and assessment of trainees, c) who has agreed to;
 - provide the student with opportunities to develop competencies in prescribing
 - supervise, support and assess the student during their clinical placement.

Pharmacists would normally be expected to complete the full training programme. All candidates, however, would be required to complete all assessments, including satisfactory completion of the period of learning in practice.

AIM

To prepare pharmacists to practise as supplementary prescribers and to meet the standards set by the Royal Pharmaceutical Society of Great Britain.

LEARNING OUTCOMES

By the end of the training programme, pharmacists will be able to:

- Develop an effective relationship with the Independent Prescriber, patient and wider care team
- Demonstrate their ability to communicate and consult effectively with patients and carers
- Demonstrate their ability to conduct a relevant physical examination of patients with those conditions for which they may prescribe
- Demonstrate the ability to monitor response to therapy and modify treatment or refer the patient as appropriate
- Demonstrate how to assess patients' needs for medicines, taking account of their wishes and values in prescribing decisions
- Demonstrate how they will prescribe safely, appropriately, clinically and cost effectively
- Identify sources of information, advice and decision support and explain how they will use them in prescribing practice taking into account evidence based practice and national / local guidelines
- Recognise, evaluate and respond to influences on prescribing practice at individual, local and national levels

- Develop and document a clinical management plan within the context of a prescribing partnership
- Demonstrate an understanding of the legal and professional framework for accountability and responsibility in relation to supplementary prescribing
- Demonstrate a reflective approach to continuing professional development of prescribing practice.

INDICATIVE CONTENT

It is expected that education providers will use the indicative content to develop a detailed programme of study which will enable pharmacists to meet the learning outcomes.

Consultation and Decision-Making

- Accurate and effective communication and consultation with professionals, patients and their carers
- Building and maintaining an effective relationship with patients, parents and carers taking into account their values and beliefs
- Understands own limitations
- A knowledge of the range of models of consultation and their applications
- Development and documentation of a clinical management plan including referral to the independent prescriber and other professionals
- Principles of diagnosis and the concept of a working diagnosis
- Management options including non-drug treatment.

Influences on and Psychology of Prescribing

- Patient demand versus patient need including partnership in medicine taking, awareness of cultural and ethnic needs
- External influences, at individual, local and national levels
- Awareness of own personal attitude and its influence on prescribing practice.

Prescribing in a Team Context

- The role and functions of other team members

- The responsibility of the supplementary prescriber in developing and delivering the clinical management plan
- The professional relationship between independent and supplementary prescribers and those responsible for dispensing
- Documentation, and the purpose of records in communicating prescribing decisions to other members of the team
- Structure, content and interpretation of medical records/clinical notes including electronic health records
- Interface between multiple prescribers and the management of potential conflict
- The framework for prescribing budgets and cost effective prescribing.

Update on relevant aspects of Basic and Applied Therapeutics

- Clinical pharmacology
- Basic principles of drug handling – absorption, distribution, metabolism and excretion
- Pharmacodynamics and pharmacokinetics
- Changes in physiology and drug response, for example the elderly, young, pregnant or breast feeding women and ethnicity
- Adverse drug reactions and interactions
- Pathophysiology of defined conditions for which the pharmacist may prescribe
- Selection of drug regimen
- Natural history and progression of defined conditions
- Impact of co-morbidities on prescribing and patient management.

Principles and methods of monitoring

- Principles and methods of patient monitoring
- Chemical and biochemical methods for monitoring the treatment of the conditions for which the pharmacist may prescribe
- Physical examination skills relevant to the conditions for which the pharmacist may prescribe

- Assessing responses to treatment against the objectives of the clinical management plan
- Working knowledge of any monitoring equipment used within the context of the clinical management plan
- Patient compliance
- Identifying and reporting adverse drug reactions.

Evidence-based Practice and Clinical Governance in relation to Supplementary Prescribing

- The rationale for national and local guidelines, protocols, policies, decision support systems and formularies – understanding the implications of adherence to and deviation from such guidance
- Supplementary prescribing in the context of the local health economy e.g. application of local priorities to supplementary prescribing, prescribing guidance produced by PCT prescribing forum, health economy Area Prescribing Committees and priorities for health improvement
- Principles of evidence-based practice and critical appraisal skills
- Reflective practice and continuing professional development – role of self and organisation
- Auditing, monitoring and evaluating prescribing practice
- Risk assessment and risk management
- Audit and systems monitoring
- Analysis and learning from medication errors and near misses.

Legal, Policy, Professional and Ethical Aspects

- Policy context for prescribing
- RPSGB Code of Ethics and Practice Guidance
- Legal basis for prescribing, supply and administration of medicines
- Medicines regulatory framework including Marketing Authorisation, the use of unlicensed medicines and “off-label” use
- Application of the law in practice, professional judgment, liability and indemnity

- Maintenance of professional knowledge and competence in relation to the conditions for which the pharmacist may prescribe
- Accountability and responsibility as a supplementary prescriber
- Accountability and responsibility to the employer or commissioning organisation, awareness of local complaints procedures
- Informed consent
- Prescription pad security and procedures when pads are lost or stolen
- Writing prescriptions
- Record keeping, documentation and professional responsibility
- Confidentiality, Caldicott and Data Protection
- Suspicion, awareness and reporting of fraud or criminal behaviour, knowledge of reporting and 'whistle blowing' procedures.

Prescribing in the Public Health Context

- Duty to patients and society
- Public health policies, for example the use of antibiotics
- Inappropriate use of medicines including misuse, under and over-use
- Inappropriate prescribing, over and under-prescribing.

TEACHING, LEARNING AND SUPPORT STRATEGIES

Teaching and learning strategies need to recognise:

- The background knowledge and experience of pharmacists in all aspects of medicines, working with patients and the law relating to pharmacy and that this will vary between individuals
- The requirement for a pharmacist to become familiar with the specified conditions for which they may prescribe and that some individual directed study may be necessary to achieve this
- The value added to learning by group work and multi-disciplinary learning experiences with other trainee supplementary prescribers
- The value of case studies and significant event analysis in the learning process

- The need to encourage development of critical thinking skills and reflective practice and the maintenance of CPD records.

Period of Learning in Practice

The sponsoring organisation e.g. a primary care organisation or NHS Trust, and the education provider must ensure that the designated medical practitioner who provides supervision, support and shadowing opportunities for the student is familiar with the requirements of the programme and the need to achieve the learning outcomes. In particular, this element of the programme should ensure that;

- The pharmacist becomes competent in the relevant physical examination of patients with those conditions for which they may prescribe
- The pharmacist is able to monitor and assess the responses of patients to treatment against the objectives in the clinical management plan
- The pharmacist demonstrates effective communication with the patient, the independent prescriber and the wider care team
- The pharmacist keeps adequate records of their prescribing practice
- The pharmacist demonstrates and documents their professional development as a supplementary prescriber.

ASSESSMENT STRATEGIES

The assessment requirements must be made explicit, in particular the criteria for pass/fail and the details of the marking scheme.

Assessment should test all aspects of supplementary prescribing, both theory and practice. The learning outcomes should be assessed by a combination of methods to test knowledge, skills and a reflective approach to the continuing professional development of prescribing practice (e.g. by written examination, OSCE, reflective journal). Each student should maintain a portfolio of assessment and achievement of the stated learning outcomes.

The assessment strategies should test:

- a) Knowledge and skills relevant to supplementary prescribing
- b) Ability to work with patients and make prescribing decisions
- c) Ability to conduct the relevant physical examination of patients for whom they can prescribe
- d) A reflective approach to learning and CPD as a supplementary prescriber

- e) Satisfactory completion of the period of practice experience*

*Completion of the programme and confirmation of an award must be conditional on satisfactory completion of the practice experience. Poor performance in this element must not be compensated by other elements of the assessment.

LENGTH OF PROGRAMME

The duration of the programme is expected to be at least 25 days, of which a substantial proportion will be face-to-face contact time. Other ways of learning, such as open learning formats will be considered. In finalising programme requirements for this curriculum, the following factors will be taken into account;

- The views of education providers on a realistic programme length to deliver the curriculum effectively over a period of three to six months. Current practice in training nurse prescribers is approximately 27 days contact time over six months plus the equivalent of one day per week learning in practice. A total of approximately 37 days
- The compatibility of programmes for nurses, pharmacists and supplementary prescribers from other disciplines so that at least some of the learning experiences are shared
- The need for programmes for pharmacists to contain an element of directed private study on the defined conditions for which they will be expected to prescribe treatments
- The period of learning in practice for an individual pharmacist should be sufficiently long to enable the pharmacist to become competent in the skills of supplementary prescribing practice and in no case should it be less than 12 days.

November 2002

Clinical Governance Framework / Guideline for Pharmacist Prescribers

1. Ensuring the quality and safety of health care provided to patients is a priority for all health care professionals. Pharmacists now have the opportunity to provide a broader range of services to patients, and improve access and usage to medicines by becoming prescribers. Prescribing is a developing and expanding role for pharmacists and it is important that it is conducted in a safe and effective manner.
2. The Royal Pharmaceutical Society of Great Britain (RPSGB) has produced this clinical governance framework to support the development of high quality care and patient safety in this area of practice. This clinical governance framework should be used in conjunction with the competency framework for pharmacist supplementary prescribers developed by the National Prescribing Centre (NPC). Whilst this document focuses on clinical governance requirements for pharmacist prescribing, its implementation will form only part of local clinical governance arrangements for prescribing and so needs to be integrated into such arrangements.
3. The UK Health Departments have set out what steps NHS organisations are to put in place to ensure the implementation of clinical governance^{1 2 3} These include:
 - Clear lines of responsibility and accountability for overall quality of clinical care
 - Development of quality improvement programmes i.e. clinical audit, supporting evidence-based practice, implementation of clinical standards, monitoring of clinical care, workforce planning and development, putting in place CPD programmes
 - Management of risk
 - Procedures to identify and remedy poor performance
4. Ensuring patient safety is an integral part of healthcare providers' clinical governance programmes.⁴ Healthcare organisations, when putting forward pharmacists for prescribing training, should ensure existing and future clinical governance arrangements for their organisation incorporate prescribing. Chief Pharmacists/Senior Pharmaceutical Advisers of NHS Trusts and PCTs should be proactive in this respect, liaise closely with local clinical governance leads, and participate in clinical governance arrangements for prescribing.

¹ Clinical Governance: Quality in the new NHS. HSC 1999/065

² Clinical Governance Guidance WHC(99)54

³ Clinical Governance MEL(98)75

⁴ Building a safer NHS for patients: implementing an organisation with a memory. DoH 2001.

5. This guideline for pharmacist prescribing has been developed from two distinct viewpoints. Firstly from an organisational perspective looking at the organisational components of clinical governance and what might need to be put in place to support clinical governance of pharmacist prescribing. These organisations include Primary Care Trusts, NHS Trusts, the private and voluntary healthcare sector and all organisations employing PPs, and providing care to both NHS and non-NHS patients. Secondly from an individual PP point of view. This guideline provides some suggested indicators of good practice for pharmacist prescribing, and examples of good clinical governance practice relating to prescribing. Where we have identified additional/different requirements for Pharmacy Supplementary Prescribers (PSP), from pharmacist prescribers (PP) in general, these are highlighted in *italics*. Many of the recommendations in this guideline need to happen as part of wider organisational work on managing prescribing and medicines management.

6. Recommendations for Organisations involved in Pharmacist Prescribing

6.1 Recommendations for NHS Organisations

Component of Clinical Governance	Recommendation to NHS Organisations
Clear lines of responsibility and accountability for overall quality of clinical care	Pharmacist prescribing is included in reports on quality of clinical care to local Clinical Governance Committees or equivalent
	Pharmacist prescribing forms part of local organisational Clinical Governance Action Plans
Clinical audit	Clinical audit units incorporate PPs within their audit programmes
	Prescribing by <u>PPs</u> is monitored regularly using prescribing or medicines usage information systems as part of the wider monitoring of prescribing by doctors and nurses. The review should consider choice and range of medicines prescribed in relation to scope of practice. <i>In addition for <u>PSPs only</u>, prescribing is in line with clinical management plans (CMP) .</i>
Evidence based practice	Ensure that information about national guidelines (e.g. NICE guidelines), local guidelines and formularies are disseminated to all PPs
Monitoring of clinical care	Patient's experience of pharmacist prescribing is included in surveys of patient's experience of health services
Workforce planning and	Ensure that the ongoing Continuing Professional

development is integrated in organisations service planning	Development (CPD) needs of PPs are included in their workforce development plans
Risk management programmes	Pharmacist prescribing should be included in clinical risk management, patient safety (including the NPSA National Reporting and Learning Scheme) and controls assurance programmes

All of the above recommendations are equally applicable to the private and voluntary health sectors.

6.2 Recommendations for employers of pharmacist prescribers:

The table below highlights additional recommendations for all employers including non-NHS employers, e.g. pharmacy contractors, who employ PPs, who are providing services to NHS and non-NHS patients.

Component of Clinical Governance	Recommendation to Employers
Monitoring of clinical care	Pharmacist prescribers should participate in clinical governance programmes for prescribing, and be supported to do this
Continuing professional development programmes are in place	The competence framework for <i>PSPs</i> should be used to identify gaps and learning needs that should for part of the PPs personal development plans (PDP).
	PPs have will need to satisfy RPSGB requirements for CPD and should have access to programmes and resources to meet their CPD needs
	The development of peer review, support and mentoring, possibly through the development of learning sets ⁵ for pharmacist prescribers, should be supported
	<i>PSP are encouraged to have regular (normally at least annual) meetings with the independent prescribers to review CMPs</i>
Poor performance programme	All organisations employing pharmacists should have systems in place for identifying poor professional performance as for other prescribers. Prescribing should be considered as part of this process

⁵ Learning set – a group of “like” minded individuals who choose to form a group in order to undertake some form of learning together

6.3 Recommendations to individual pharmacist prescribers

The proposed indicators and examples of good clinical governance practice (Annex A) have been developed to help individual pharmacist prescribers (PP) ensure that their practice is safe and of a high standard. Patient safety is of paramount importance with the introduction of prescribing. As for other aspects of prescribing and medicines management. It is also incumbent on pharmacists as health care professionals to practice within the law, to a high professional standard, and to ensure that they strive to continuously improve the quality of care they offer to patients. Poor professional performance needs to be identified and rectified at an early stage. A clinical governance framework, used in association with the PSP competency framework, can help to identify what is good practice, by using indicators of good practice.

6.4 Suggested indicators of good practice for pharmacist prescribers

The pharmacist prescriber:

1. Communicates with patients in a way that allows the pharmacist prescriber to understand the patient's needs, concerns and expectations about their medicines and enables the patient to make an informed choice about their treatment (including the risks and benefits).
2. Prescribes within their own competence and within their own scope of practice
3. Writes prescriptions clearly and legibly, and ensures that they are identifiable as the prescriber.
4. Prescribes only when they have access to an individual patient's main, up to date, primary care, or secondary care medical record, at the time of prescribing. In the future this will be accessed via an individual patient's Electronic Patient Record
5. Makes a contemporaneous, comprehensive, clear record of their consultation and prescription for an individual patient in the main medical record. Where it is not possible for a PP to make a contemporaneous record in the main medical record, the PP should make a contemporaneous record, which is then added to the main medical record within 24 or 48 hours of the consultation.
6. Keeps prescription pads safely and takes appropriate action if they are lost or stolen

7. Must not ask for or accept any inducement, gift or hospitality which may affect or be seen to affect their judgement when making a prescribing decision
8. Regularly participates in CPD relating to supplementary prescribing and maintains a record of their CPD activity within their CPD portfolio
9. Where the pharmacist is both prescribing and dispensing for an individual patient, a suitably competent second person (as designated in the pharmacy Standard Operating Procedure) should be involved in accuracy checking of the medicine. It is good practice for the pharmacist to carry out a check of the validity, safety and clinical appropriateness of their prescription

Additional indicators for PSPs

- 10. Prescribes according to the clinical management plan (CMP) agreed with the Independent Prescriber, for an individual patient.*
- 11. Refers all individual patient circumstances that fall outside the clinical management plan to an Independent Prescriber who is responsible for that patient's care.*

Annex A Examples of Good Clinical Governance Practice

The final section of this guideline has been developed using the “Seven Pillars of Clinical Governance”⁶ and from the main components of clinical governance identified in HSC 1999/065 (England)¹ WHC (99) 54 (Wales)² and MEL(98)75³ (Scotland). In addition to indicators of good practice given above we have identified a number of examples of good clinical governance practice relating to prescribing which PPs and organisations may wish to aspire to. These examples are listed below.

Component of Clinical Governance	Exemplar clinical governance practice for pharmacist prescriber	Examples of Evidence
Clear lines of responsibility and accountability for overall quality of clinical care	PP agrees with the independent prescriber how continuity of patient care is maintained when they are not available (I.e. annual leave, sick leave)	Written procedure in place
	PP is aware of, and complies with local, national and professional standards relating to dealing with the pharmaceutical industry	PP declaration of interests held by Trust or employer
Clinical audit	PP participates in local clinical audit activity relating to their scope and quality of prescribing practice e.g. asthma audit.	Report of outcome of audit
	Audit/CG arrangements should allow pharmacists to reflect on their prescribing practice	Reflected learning is recorded in CPD record
Clinical Guidelines and Evidence based practice	PP keep up to date with and prescribe according to local or national standards and guidelines, with reference to best evidence	Results of procedures for monitoring and auditing prescribing patterns. Reflective learning included in CPD portfolio
	<i>Patient specific CMPs are developed and kept up to date. CMPs will refer to national and local guidelines where appropriate.</i>	<i>Within CMPs guidelines are referenced, and CMPs include date of development and date of review</i>
Continuing	PP maintains a CPD portfolio,	Reflective learning

⁶ NHS Clinical Governance Support Team www.cgusupport.org.uk

¹ Clinical Governance - Quality in the new NHS. HSC 1999/065

² Clinical Governance Guidance WHC(99)54

³ Clinical Governance MEL(98)75

professional development	including a review of prescribing related critical incidents and learning from them	included in CPD portfolio
	PPs participates in local prescriber learning set or peer support group	Reflective learning included in CPD portfolio
	PPs, in conjunction with their line managers, identifies training needs in relation to prescribing, and identifies ways of meeting these needs	Training needs identified in CPD portfolio or PDP, and evidence of learning and development undertaken recorded
	<i>PSP participates in regular (normally at least annually) meeting with the independent prescriber to review CMP, discuss working arrangements and review patient care</i>	<i>Learning points from this meeting are included in the PSP's CPD portfolio</i>
		<i>Notes of the meeting are made and identify action required</i>
		<i>Where possible Independent prescriber contributes to the PSP annual appraisal by their line manager</i>
Monitoring of clinical care	PPs participate in audits of clinical record keeping and medicines monitoring information.	Report of outcome of audit, reflective learning included in CPD portfolio
	PPs participates in audits of the communication pathways they use, to ensure the correct patient information (relating to prescribing) is included in a timely manner in patients medical notes, or when care is transferred to another prescriber	Report of outcome of audit
	PPs audits whether individual patients have received enough information about their prescribed medication	Report of outcome of audit using SIMS tool ⁷
Research and Development	PPs reviews their practice with a view to research potential	Outcome of research

⁷ Horne R, Hankins M, Jenkins R. The Satisfaction with Information about Medicines Scale (SIMS): a new measurement tool for audit and research. Qual Health Care 2001;10:135-140.

Risk management	PPs participates in a local clinical risk assessment and management programme	Copy of local policy held by PPs and systems are developed for formal recording of risks and evaluation of risk arising from prescribing decisions
	PPs participates in, and reports critical incidents as part of the local critical incident reporting system (including the NPSA National Reporting and Learning Scheme)	Record of critical incidents reported by PPs
	PPs are aware of local patient complaints procedures	Copy of local complaints procedure held by PPs
	PPs use complaints and compliments to identify learning needs and areas for improvement.	Reflective learning included in CPD portfolio

Appendix 5

Common/Minor Ailment Schemes

A *Sefton*-based intervention study^{6,7} has evaluated the outcomes of removing economic barriers to self-care, arising from prescription charge exemption. A community pharmacy based model of service provision for the treatment of twelve minor ailments was established ('The Care in the Chemist Scheme'), and the service compared with that provided in general practice. A formulary was developed for use by pharmacists so that patients received the same or similar products from them as they would from the GP. During the intervention period, 38% of minor ailment presentations at a GP practice were referred by reception staff to 12 participating community pharmacies. Some minor ailments, for example head lice and vaginal thrush, were more amenable to transfer than others. Important factors in using the scheme were accessibility, convenience and access to treatment. The authors suggest that such schemes could be developed and expanded to benefit more patients, but caution against the wholesale transfer of minor ailment management as this would not be appropriate for all patients nor for all minor ailments. The overall costs of the pharmacy scheme were not substantial; overall prescribing costs did not increase.

A self-care scheme in *Tyne & Wear*⁸ involved patients seeking appointments with their GP for respiratory tract infections, gastrointestinal problems, hay fever and thrush, being directed to their local pharmacy. Apart from the practice providing information and self-care advice, vouchers were issued, which could be redeemed for medicines at the pharmacy if necessary. Pharmacists could advise patients on which medicines they needed, whether OTC or POM, and prescribe from a formulary previously agreed with local GPs, in cases where this was appropriate.

In *Scotland*, a 'Direct Supply of Medicines Scheme'¹⁰ has enabled patients exempt from prescription charges to consult a community pharmacist and receive OTC medicines free of charge under the NHS. These patients could register with a local participating community pharmacy. Pharmacists used an agreed limited formulary. A year-long evaluation of the project was conducted in two areas of Scotland. Findings showed: uptake of the scheme was lower than expected; there was wide variation in the consultation rates achieved by participating pharmacies; 73% pharmacy consultations were for those exempt by age; head lice was the most common condition presented, followed by pain and cough; a minority of users objected to the busy environment and lack of privacy in some pharmacies.

The generally positive experience from this pilot, plus further extended monitoring¹¹ has informed an imminent, wider roll-out of the scheme.

