CONSULTATION ON PROPOSALS TO INTRODUCE INDEPENDENT PRESCRIBING BY PHARMACISTS

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CONSULTATION ON PROPOSALS TO INTRODUCE INDEPENDENT PRESCRIBING BY PHARMACISTS

Introduction

1. We are writing to consult you in accordance with section 129(6) of the Medicines Act 1968 about proposals to enable pharmacists to become independent prescribers. This would be achieved by amendment to the Prescription Only Medicines (Human Use) Order 1997 (the “POM” Order) and consequential amendments to NHS legislation.

2. This consultation document has been jointly produced by the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Department of Health. It is also being made available in Wales, Scotland and Northern Ireland. The consultation abides by the six consultation criteria set out in the revised Code of Practice on Consultation published by the Cabinet Office (www.cabinet-office.gov.uk/regulation/Consultation/Code.htm).

Application to England, Wales, Scotland and Northern Ireland

3. The proposed changes to the POM Order would apply throughout the United Kingdom both in the NHS and in the independent and voluntary sectors. However, the focus and pace of development of pharmacist independent prescribing and the arrangements for training within national health organisations, are matters for each of the separate administrations. Pharmacist independent prescribing introduced by health care organisations outside the NHS would have to comply with legislative requirements. Those organisations should also consider developing accompanying guidance similar to that which will apply to the NHS, or endorse the NHS guidance.

Timing and Process

4. This consultation remains open for 12 weeks and responses should be sent to arrive no later than 25 May 2005.

5. A proforma is attached at Annex E which you may find helpful in preparing your response. We would very much welcome your views on the issues raised in this document.
6. Following the close of consultation, the Committee on Safety of Medicines (CSM) will be asked to consider the proposals in the light of comments received and taking into account views expressed by the devolved administrations. CSM’s advice will be conveyed to Ministers. Subject to the agreement of Ministers, we plan to implement changes by Statutory Instrument later in 2005. Statutory Instruments are available from the Stationary Office and may also be viewed on their website http://www.hmso.gov.uk.

Background

7. In 1997, the Government set up a Review of Prescribing, Supply and Administration of Medicines (under the Chairmanship of Dr June Crown). In 1999, the second report\(^1\) of the Review recognised the potential for an extension of prescribing responsibilities to health professionals other than doctors, dentists and the then small number of independent nurse prescribers. As a result, a wider formulary for nurse prescribing (the Nurse Prescribers’ Extended Formulary) was introduced in 2002.

8. In April 2003, the Government also enabled nurses and pharmacists to become supplementary prescribers (i.e., working in partnership with an independent prescriber within an individual clinical management plan (CMP)). Medicines legislation will shortly be amended to enable podiatrists, radiographers, physiotherapists and optometrists to become supplementary prescribers.

Rationale

9. It is Government policy to extend prescribing responsibilities beyond those currently authorised to do so in order to:-

- improve the quality of service to patients without compromising patient safety;
- make it easier for patients to get the medicines they need;
- increase patient choice in accessing medicines;
- make better use of the skills of health professionals;
- contribute to the introduction of more flexible team working across the NHS.

Principles Underpinning the Expansion of Prescribing Responsibilities

10. Previous public consultations on nurse prescribing in 2000 and 2001 and discussion with consumer groups and the health professions has led to broad agreement about the principles which should guide the extension of prescribing responsibilities. These principles remain good for all health professionals and are:

- patient safety will be paramount;
- professionals will be expected to act within their professional code of conduct and only prescribe where they feel fully competent to do so;
- changes to prescribing arrangements will occur where this provides better and more convenient care for patients;
- local decisions on training (within a nationally agreed curriculum) and service commissioning will be driven by patient and local service need;
- independent prescribers will take full clinical responsibility for their decisions;
- dispensing pharmacists and those charged with prescription re-imbursement need to be able to identify easily those individuals entitled to prescribe;
- national policy on extension of prescribing responsibilities, in the context of devolved government, should provide a framework to help manage patients’ medical conditions, and provide convenient access to treatment.

11. This consultation will help to determine:

- whether any restrictions should be placed on prescribing in terms of medical conditions and/or range of medicines that might be used;
- the requirements of the different ranges of prescribing; activity in the different sectors where pharmacists work;
- what kind of training and support is needed;
- which individuals will be considered to go forward for prescribing training.

Definition of an Independent Prescriber

12. The Crown Report described independent prescribers as professionals who are responsible for the initial assessment of the patient and for devising the broad treatment plan, with the authority to prescribe the medicines required as part of that plan. We have defined an independent prescriber as:
“.....a practitioner (eg doctor, nurse, pharmacist) responsible for the assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical management required, including prescribing.”

13. **QUESTION** We would welcome views on whether this definition is suitably robust and encompasses all situations in which pharmacists will need to prescribe.

**Benefits of Extending Prescribing Responsibilities To Pharmacists**

14. Nurses, midwives and health visitors have been independent prescribers for some time. Some pharmacists have already completed prescribing training and are taking on roles as supplementary prescribers. It makes sense to use their considerable skills in pharmacology and therapeutics further in taking on independent prescribing responsibilities.

15. Patients will benefit from greater access to pharmacists’ knowledge and expertise and from a speedier and more accessible service. They may often be able to consult a pharmacist directly, much as they currently do for “over the counter” products, rather than make separate visits to see a doctor and a pharmacist. Discharges from hospital may be expedited if pharmacists, who work as part of multi-disciplinary teams, can prescribe and supply appropriate medicines around the time of discharge, without having to wait for a doctor to sign a prescription. Patient care could also benefit if pharmacists were able to prescribe medicines on admission to hospital having taken a detailed medication history. There is evidence to show that pharmacists taking medication histories on admission have identified gaps and their interventions have led to improved patient safety.

16. Access to treatment could also be speeded up as medication reviews carried out by pharmacists could lead directly to revised prescriptions without the need to wait for medical intervention. Pharmacists working within multi-disciplinary teams could significantly improve the management of long-term conditions and patient care by being able to prescribe and take responsibility for that prescribing decision instead of having to wait for a doctor to sign a prescription for a medicine and dose which has been recommended by the pharmacist.
17. Patients and the NHS will benefit as some consultations will be diverted to pharmacists and the time and energies of the doctors, and other professionals concerned, could therefore be focussed more clearly on the areas and patients that most need their expertise.

18. Pharmacists will benefit from the opportunity to use their skills more widely and develop them further, whether they work within the NHS or within the independent healthcare sector.

19. Independent prescribing by pharmacists could help achieve the primary care access targets. In hospitals, specialist clinical pharmacists are already pro-actively influencing prescribing decisions and are often making prescribing recommendations but are not themselves able to prescribe. Introducing independent prescribing will enable pharmacists to carry through their recommendations and be accountable for them.

20. **QUESTION** We would welcome views on the benefits to be gained from the introduction of independent prescribing by pharmacists.

**Range of Settings Where Pharmacists Work**

21. Like many other healthcare professionals, pharmacists work in a number of distinct areas where their working scope and practices can be quite different. Wherever they work, they are engaged with patients to help them use their medicines safely and effectively. Examples include, helping patients understand more about their medicines and how to take them, identifying and addressing compliance issues, reviewing medication, and solving or preventing problems patients have with their medicines.

22. Many pharmacists work in secondary care supporting highly specialised teams, for example delivering cancer care or services for people with HIV/ AIDS. They also help develop treatment guidelines, are key members of drugs and therapeutics committees, and manage outpatient and inpatient services.

23. In the community, pharmacists work in a variety of settings, where they not only dispense medicines prescribed by independent and supplementary prescribers, but are also an important source of advice to both patients and prescribers. They are often able to recommend strategies or preparations for effective self-care and support public health initiatives such as smoking cessation, providing both advice and products such as
nicotine replacement therapy, methadone administration supervision, provision of emergency hormonal contraception and compliance assessment. In many areas pharmacists offer NHS minor ailments schemes, which take some pressure off GPs and improve the availability of care for patients.

24. In some instances pharmacy and GP premises are part of the same primary care centre. Some pharmacists work more directly with GPs, carrying out reviews of prescribing and medication and they are increasingly being commissioned to run specific clinics such as hypertension clinics, anticoagulant clinics and hyperlipidaemia clinics.

25. The new contractual frameworks for community pharmacy being developed in the four countries of the UK builds on these initiatives and encourages delivery of a wider range of services.

26. Independent prescribing will add considerably to the range and convenience of services that pharmacists can provide, but the different work settings may mean that different arrangements may need to be in place for pharmacists prescribing within them.

27. **QUESTION** We would welcome views on whether different prescribing frameworks might apply to different work settings. What in your view are the key issues that should drive such a decision?

**Options For Introducing Independent Prescribing**

28. There are a range of options for the introduction of independent prescribing for pharmacists and these are outlined in greater detail in the following paragraphs.

**Option 1: No Change**

29. Pharmacists would continue to be able to supply and administer medicines under Patient Group Directions and to train to become supplementary prescribers. They would also be able to supply and sell “over the counter” – Pharmacy and General Sales List medicines.

30. **QUESTION** We would welcome views on whether it is feasible and beneficial to make no change.

**Option 2: Prescribing For Certain Conditions from a Limited Formulary**
31. Under this option, pharmacists would mirror the principles of extended nurse prescribing by being able to prescribe independently for a certain range of conditions from a limited formulary. This would place pharmacists in the same position as nurse prescribers who use the Nurse Prescribers’ Extended Formulary. It would enable them to expand the range of services they can offer in the community and primary care but is unlikely to meet the service needs of hospitals.

32. As a reminder, a list of the conditions treatable by extended nurse prescribers and a copy of the formulary are at Annex A.

33. **QUESTION** We welcome your views on whether pharmacists should prescribe for certain conditions from a limited formulary.

34. **QUESTION** We would welcome your views on the suitability of the NPEF and list of conditions for pharmacist independent prescribing. Are there conditions or medicines that should be added or deleted and what are your recommendations?

**Option 3: Prescribing for Any Condition from a Limited Formulary**

35. Under this option, pharmacists would be able to prescribe from a certain range of medicines for any relevant medical condition for which that medicine is appropriate (as per the British National Formulary) and provided that the management of that condition was within their competence. There would be no specific list of conditions but within this option it would be possible to exclude certain conditions if it was felt they should never be treated by a pharmacist.

36. **QUESTION** We would welcome your views on whether pharmacists should prescribe for any condition from a limited formulary. Are there any conditions that should be excluded and what are your recommendations?

37. **QUESTION** We would welcome your views on the suitability of the Nurse Prescribers Extended Formulary for pharmacist independent prescribing. Are there medicines that should be added or deleted and what are your recommendations?

**Option 4: Prescribing for Specific Conditions from a Full Formulary**

38. Pharmacists would be able to prescribe any medicine from the British National Formulary, but only for a specific range of
conditions. Within this option it would be possible to restrict the ability to prescribe any medicines deemed inappropriate.

39. **QUESTION** We would welcome views on whether pharmacists should prescribe from the full British National Formulary for a specific set of conditions. In particular, what specific conditions, over and above those currently treatable by extended nurse prescribers (Annex A) should be treated by independent prescriber pharmacists?

**Option 5 : Prescribing For Any Condition from a Full Formulary**

40. Pharmacists would be able to prescribe any medicine from the British National Formulary for any condition. If this option were adopted it could be modified to restrict the ability to prescribe any medicines deemed inappropriate for independent prescribing by pharmacists.

41. **QUESTION** We would welcome views on whether pharmacists should prescribe for any condition from the full British National Formulary. In particular, do you have any views on classes of medicines which you would consider inappropriate for prescribing by pharmacists?

**Option 6 : Different Approaches for the Different Clinical Settings**

42. This option would allow different approaches to be adopted according to the setting where the pharmacist was prescribing, i.e. in hospital, primary care or in the community. It would allow the different natures of these environments to be accommodated in a way that was safe for patients and made the best use of pharmacists’ skills. It might, for example, be safe and effective to enable hospital pharmacists to prescribe from the full BNF so that they could operate effectively within highly specialised areas. On the other hand, such a range of medicines may not be needed in the community where a formulary similar to the NPEF could meet patients’ needs.

43. **QUESTION** We would welcome views on whether a different approach to independent prescribing by pharmacists should be adopted for different clinical settings.

**Option 7: A Hybrid Approach**

44. This option would allow hospital pharmacists and community and other primary care based pharmacists, who have been presented with a diagnosis from the patient’s general practitioner
or hospital consultant, to prescribe from the full BNF. Community and primary care based pharmacists without access to a diagnosis would be able to prescribe from an agreed formulary, similar to the NPEF. The benefit of this approach would be to harness the pharmacist’s extensive knowledge of medicines and their use to improve drug and formulation selection for individual patients.

45. **QUESTION** We would welcome views on whether pharmacists should be able to prescribe any medicines from the BNF provided that a diagnosis has already been made by a GP or consultant, and from an agreed formulary where there is not access to a diagnosis.

Further General Questions

46. **QUESTION** Which option would you favour overall and why?

47. **QUESTION** If we adopted any of options 3 to 7 this would mean that there were differences in the rules governing independent prescribing by pharmacists and nurses, ie pharmacist prescribing would not be restricted to particular conditions. Are there reasons why a different approach should be taken to independent prescribing by pharmacists and what are they?

Which Pharmacists will prescribe?

48. Training for prescribing in the NHS will be funded and commissioned through the workforce directorates of SHAs in England and their equivalents in Scotland, Wales and Northern Ireland. Employers will identify who needs to be trained on the basis of service need and individual capability, capacity and preference. People who undertake training at NHS expense should be able to take on prescribing responsibilities as soon as they qualify, both in terms of it being part of their job and also in terms of having access to a budget to meet the costs.

49. NHS bodies will be responsible for introducing independent prescribing by pharmacists within their organisations. In doing so, they will have regard to the needs of their population, safety issues – especially adequate access to the patient record - and resource consequences. Each of the four UK countries will determine the most appropriate approach to supporting this initiative in line with their own health policy and NHS systems and in line with UK-wide medicines legislation.
How Will Pharmacists Be Trained?

50. Pharmacists now receive 1000 hours of teaching in the undergraduate curriculum on the actions and uses of medicines – this is a European Union requirement. Training programmes are already in place to train pharmacists as supplementary prescribers.

51. The Royal Pharmaceutical Society of Great Britain (RPSGB) and the Pharmaceutical Society of Northern Ireland (PSNI), the regulatory bodies for pharmacists, will be asked to develop an outline curriculum in consultation with medical and nursing professions and other stakeholders. The existing curriculum for supplementary prescribing will be a useful starting point but it will be important to ensure that the new curriculum fully reflects the wider requirements of independent prescribing and the option from this consultation that is ultimately adopted.

52. It may be desirable to develop a single curriculum which will enable pharmacists to be trained both as independent and supplementary prescribers as is the case with extended formulary nurse prescribers.

53. Training will be delivered by Higher Education Institutions (HEIs) against the outline curriculum. Their programmes will be accredited by the RPSGB or PSNI and the appropriate NHS Education and Training Authorities.

54. Employers will need to have arrangements in place to satisfy themselves that individual pharmacists have the appropriate skills and expertise to prescribe effectively and safely.

Professional Regulation

55. Once individuals have qualified to prescribe, an entry will be placed on the RPSGB or PSNI register against their name to show that they are qualified. If different approaches to prescribing are taken in hospital, primary care and the community, the register may need to show which area an individual may prescribe in. Prescribing would become part of an individual’s requirements for continuing professional development and they will be expected to show that they are maintaining their skills and keeping them up-to-date.

56. As with other healthcare professionals in the NHS, pharmacists will be expected to work only within their level of professional competence and where appropriate, to seek advice
and make referrals to other professionals with the appropriate expertise. The RPSGB or PSNI will take action when pharmacists do not maintain appropriate professional standards and ethics in their prescribing practice.

**Ensuring Safety**

**Clinical governance**

57. Pharmacists who exercise prescribing responsibilities should follow the framework for clinical governance provided by their employing authority and/or professional body.

**Prescribing & dispensing**

58. Separation of prescribing and dispensing can provide an important safety check, e.g. to check that the correct identity details have been used and that appropriate preparations and dosages have been applied. Hard and fast rules on this can mean a loss of flexibility and run counter to aims of improving access to medicines for patients. Guidance on supplementary prescribing recommends that prescribing and dispensing are carried out by separate individuals wherever possible. However, in exceptional circumstances the two can co-exist provided there is a final accuracy check carried out by another individual and that there are appropriate clinical governance and audit arrangements in place.

59. As with supplementary prescribing, pharmacists will be required to monitor patients’ response to treatment and to report any adverse drugs reactions to the Committee on Safety of Medicines.

60. **QUESTION** Should the same advice on the separation of prescribing and dispensing be given to pharmacist independent prescribers as is given to supplementary prescribers? Is this sufficient to ensure safety? Are there any other practical arrangements that could be made to improve this?

**Access to the patient record**

61. It is vital that all prescribers have full access to the necessary information to enable them to make informed and safe decisions about an individual’s treatment. They must also be able to record details of any interventions they make, so that other professionals involved also have the full information they need to do their jobs safely. At present, pharmacists working in hospitals
are able to access the records they need. Pharmacists working in GP practices will also usually have access to the patient record through the GP systems. However, in community pharmacy this is not always possible. In due course, all pharmacists who are prescribers will have access to the patient record through the National Programme for IT. Until that part of the NHS IT programme is in place, bodies setting up prescribing services involving pharmacists must satisfy themselves that pharmacists have full access to all the information they will need to prescribe safely and effectively.

Guidance

62. The DH has issued detailed guidance on the implementation of the Nurse Prescribers’ Extended Formulary and Supplementary Prescribing (www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en). Similar guidance will be prepared for independent prescribing by pharmacists.

63. **QUESTION** Have you any suggestions for improving the guidance or any other practical arrangements to help ensure effective implementation and patient safety?

Regulatory Impact Assessment

64. A partial regulatory impact assessment is at **Annex B. Comments are sought on this assessment.**

Circulation of Proposals

65. This consultation letter is being sent in hard copy to those organisations listed at Annex D. This list is not exhaustive. Copies of the consultation are also available from our websites - www.mhra.gov.uk and www.dh.gov.uk/consultations – and replies are welcome from all interested parties. The DH/MHRA will not enter into correspondence about the proposals contained in this consultation.

66. A form is attached for your reply. Comments should be addressed to: **Roy Drepaul, 16/139, Medicines and Healthcare Products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London, SW8 5NQ. Alternatively, they may be e-mailed to: roy.drepaul@mhra.gsi.gov.uk**. Comments must arrive no later than 25 May 2005. Comments received after this date will not be taken into account.
Making copies of the replies available to the public

67. To help informed debate on the issues raised by this consultation, and within the terms of the Code of Practice on Access to Government Information, the Agency intends to make publicly available copies of comments that it receives. Copies will be made available as soon as possible after the public consultation has ended.

68. The Agency’s Information Centre at Market Towers will supply copies on request. An administrative charge, to cover the cost of photocopying and postage, may be applied. Alternatively, personal callers can inspect replies at the Information Centre by prior appointment (telephone 0207 084 2351).

69. It will be assumed that your comments can be made publicly available in this way, unless you indicate that you wish all or part of them to be treated as confidential and excluded from this arrangement.

Medicines & Healthcare Products Regulatory Agency
Department of Health
March 2005
Annex A


List of Conditions [Note: subject to Parliamentary approval, we anticipate that further conditions, particularly for emergency care, will be added in Spring 2005]

Circulatory
   Haemorrhoids
   Phlebitis – superficial

Ear
   Furuncle
   Otitis externa
   Otitis media
   Wax in ear

Endocrine
   Hypoglycaemia

Eye
   Blepharitis
   Conjunctivitis, allergic
   Conjunctivitis, infective
   Local anaesthetic for ophthalmic conditions

Gastro-intestinal conditions
   Constipation
   Gastro-enteritis
   Heartburn
   Infantile Colic
   Worms – threadworms

Immunisations
   Routine childhood and specific vaccinations

Musculoskeletal
   Back pain - acute, uncomplicated
   Neck pain - acute, uncomplicated
   Soft tissue injury
   Sprains

Oral conditions
   Aphthous ulcer
Candidiasis, oral
Dental abscess
Gingivitis
Stomatitis

**Respiratory**
- Acute attacks of asthma
- Acute nasopharyngitis (coryza)
- Laryngitis
- Pharyngitis
- Rhinitis, allergic
- Sinusitis, acute
- Tonsillitis

**Skin**
- Abrasions
- Acne
- Animal and human bites
- Boil/carbuncle
- Burn/scald
- Candidiasis, skin
- Chronic skin ulcer
- Dermatitis, atopic
- Dermatitis, contact
- Dermatitis, seborrhoeic
- Dermatophytosis of the skin (ringworm)
- Herpes labialis
- Impetigo
- Insect bite/sting
- Lacerations
- Local anaesthetic for occasions when procedure requires it
- Local anaesthetic for suturing of lacerations
- Nappy rash
- Pediculosis (head lice)
- Pruritus in chicken pox
- Scabies
- Urticaria
- Warts (including verrucas)

**Substance Dependence**
- Smoking cessation

**Urinary system**
- Urinary tract infection (women) - lower, uncomplicated

**Female genital system**
- Bacterial vaginosis
Candidiasis, vulvovaginal
Contraception
Dysmenorrhoea
Emergency Contraception
Laboratory confirmed uncomplicated genital chlamydia infection (and the sexual partners of these patients)
Menopausal vaginal atrophy
Preconceptual counselling
Trichomonas vaginalis infection (and the sexual partners of these patients)

Male genital system
Balanitis

Palliative Care
Anxiety
Bowel colic
Candidiasis, oral
Confusion
Constipation
Convulsions and restlessness
Cough
Dry mouth
Excessive respiratory secretions
Fungating malodorous tumours
Muscle spasm
Nausea and vomiting
Neuropathic pain in palliative care
Pain control
List of medicines as at February 2005. [Note: subject to Parliamentary approval, we anticipate that further medicines, particularly for emergency care, will be added in Spring 2005]

<table>
<thead>
<tr>
<th>Drug</th>
<th>Route of administration, use or pharmaceutical form</th>
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<tbody>
<tr>
<td>Aciclovir</td>
<td>External</td>
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<td>Acrivastine</td>
<td>Oral</td>
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<tr>
<td>Adapalene</td>
<td>External</td>
</tr>
<tr>
<td>Alclometasone dipropionate</td>
<td>External</td>
</tr>
<tr>
<td>Alimemazine tartrate (trimeprazine tartrate)</td>
<td>Oral</td>
</tr>
<tr>
<td>Amitriptyline hydrochloride</td>
<td>Palliative care – oral</td>
</tr>
<tr>
<td>Amorolfine hydrochloride</td>
<td>External</td>
</tr>
<tr>
<td>Amoxycillin trihydrate</td>
<td>Oral</td>
</tr>
<tr>
<td>Aspirin</td>
<td>Oral</td>
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<tr>
<td>Azelaic acid</td>
<td>External</td>
</tr>
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<td>Azelastine hydrochloride</td>
<td>Ophthalmic, nasal</td>
</tr>
<tr>
<td>Azithromycin dihydrate</td>
<td>Oral</td>
</tr>
<tr>
<td>Baclofen</td>
<td>Palliative care – oral</td>
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<tr>
<td>Beclometasone dipropionate</td>
<td>External, nasal</td>
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<tr>
<td>Betamethasone sodium phosphate</td>
<td>Aural, nasal</td>
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<td>Betamethasone valerate</td>
<td>External, rectal</td>
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<tr>
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<td>Nasal</td>
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<td>Carbamazepine</td>
<td>Palliative care – oral,rectal</td>
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<td>External</td>
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<td>Clavulanic Acid</td>
<td>Oral</td>
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<td>Clindamycin phosphate</td>
<td>External, vaginal</td>
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<td>Clolobetasone butyrate</td>
<td>External</td>
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<td>External</td>
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<td>Codeine phosphate</td>
<td>Oral</td>
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<td>Conjugated oestrogens (equine)</td>
<td>External</td>
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<td>Co-phenotrope</td>
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<td>Cyclizine</td>
<td>Palliative care - parenteral</td>
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<td>Diazepam</td>
<td>Palliative care – oral, parenteral and rectal</td>
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<td>Diclofenac diethylammonium</td>
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<td>Oral, rectal</td>
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<td>Domperidone</td>
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<td>Oral</td>
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Partial Regulatory Impact Assessment

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

Issue

1. The Government is committed to improving patients’ access to NHS prescription medicines and making better use of the skills of NHS professionals, while freeing up time for GP appointments. This was set out in the NHS Plan July 2000 and the NHS Improvement Plan July 2004.

Objective

2. The aim of these proposals is to enhance patient care by improving access to treatment and advice through an increased and more flexible use of pharmacists’ professional skills. The changes proposed to medicines legislation will apply to activities undertaken by pharmacists working in or for the National Health Service (NHS) or otherwise publicly funded health services throughout the United Kingdom and also to the independent and voluntary healthcare sectors.

Scope of this RIA

3. The extent to which independent prescribing is adopted within national health organisations is a matter for each of the devolved administrations. These national services are not regarded as a “business, charity or voluntary organisation” for the purpose of this RIA. Independent Prescribing may also be appropriate for health services provided by the Defence Medical Services and the Prison Services. These services are also not regarded as a “business, charity or voluntary organisation” for the purpose of this RIA.

4. Health services provided outside the NHS and publicly funded health services and the service provided by community pharmacists, (excluding, for the purpose of this RIA, their NHS business operations), are regarded as businesses and the RIA therefore concentrates on the impact of the proposed changes on these groups (referred to from now on as the
independent healthcare sector). However, Independent Prescribing does not create a new regulatory environment with which the independent healthcare sector must comply at the outset. Whether businesses, employers and individual health professionals enter into Independent Prescribing is entirely a voluntary decision for them based on their commercial and professional judgement.

Background

5. In 1997, the Government set up a Review of Prescribing, Supply and Administration of Medicines (under the Chairmanship of Dr June Crown). In 1999, the second report of the Review recognised the potential for an extension of prescribing responsibilities to health professionals other than doctors, dentists and the then small number of independent nurse prescribers. As a result, a wider formulary for nurse prescribing (the Nurse Prescribers’ Extended Formulary) was introduced in 2002.

6. It is Government policy to extend prescribing responsibilities beyond those currently authorised to do so in order to:-

   • improve the quality of service to patients without compromising patient safety;
   • make it easier for patients to get the medicines they need;
   • increase patient choice;
   • free up the time of doctors to carry out other clinical work
   • make better use of the skills of health professionals;
   • contribute to the introduction of more flexible team working across the NHS.

7. Pharmacists are currently able to sell and supply medicines classed in medicines legislation as “general sales list” – medicines which can be sold from lockable premises and “pharmacy” – medicines which can be sold in pharmacies by or under the supervision of a pharmacist. Pharmacists are also one of the professions who can supply and administer medicines via Patient Group Directions (PGDs). A PGD is a written instruction for the sale, supply or administration of named medicines in an identified clinical situation. It applies to groups of patients who may not be individually identified before presenting for treatment.

8. In April 2003, the Government also enabled nurses and pharmacists to become supplementary prescribers (i.e., working in partnership with an independent prescriber within
an individual clinical management plan (CMP)). By February 2005 around 400 pharmacists had qualified as supplementary prescribers in the UK. Medicines legislation will shortly be amended to enable podiatrists, radiographers, physiotherapists and optometrists to become supplementary prescribers.

9. Further information on the context of the proposal is in the main body of the consultation document.

Risk Assessment

10. Introduction of independent prescribing by pharmacists will ensure that both patients and the service obtain the maximum possible benefit from pharmacists’ professional skills, including their considerable knowledge of pharmacology and therapeutics. Service to patients will improve by making it easier for them to obtain the medicines they need and the proposal could also help achieve the primary care access targets by reducing pressure on other health professionals. We would not be able to realise these benefits if this measure were not adopted.

11. Pharmacists will only prescribe where they can do so safely. They will only be able to prescribe independently once they have completed an appropriate training course and been accredited by their regulatory body. In order to maintain accreditation they will need to show that they take steps to keep their skills and knowledge current. As with all healthcare professionals, they will only work within their areas of professional competence.

12. The training which pharmacists who wish to prescribe will undertake will meet the outline curriculum set out by the regulatory bodies and will be accredited by them. Only courses which have been duly accredited will be able to award qualifications leading to prescribing status.

13. Pharmacists detailed knowledge of drugs and their interactions will make them particularly effective in avoiding and treating illness directly caused by prescribed drugs.

Options

14. Option 1 - Do nothing.
15. **Option 2 to 7** - Amend medicines legislation to enable pharmacists to act as independent prescribers.

**Benefits**

16. **Option 1** – This would maintain the status quo but would lose the benefit of patients gaining improved access to advice and treatment, without the need for a doctor’s prescription. It would not maximise the use of pharmacists skills.

17. **Option 2** – The consultation offers the following 5 choices for introducing independent prescribing by pharmacists:

- prescribing for certain conditions from a limited formulary:
- prescribing for any condition from a limited formulary;
- prescribing for certain conditions from a full formulary;
- prescribing for any condition from a full formulary;
- different approaches for different clinical settings;
- a hybrid approach

18. Each of the six options (2 to 7) would enable safe and effective practice to operate which has advantages for both patients and healthcare staff through:

- easier access to advice and treatment – pharmacists will be able to advise patients on the range of medicines options available to them and give a prescription for a prescription only medicine if that is what is required,
- increased patient choice as to which health professional they consult and where and when they do so;
- reducing waiting times for access to primary care, admission to and discharge from hospital, accessing drug therapy, eg for cancer;
- maximising use of pharmacists’ professional skills;
- diverting some consultations from doctors and nurses, enabling them to devote time to the patients who most need their particular skills; and,
- supporting the introduction of more flexible team working among health professionals.

19. Pharmacists will only be able to prescribe after appropriate professional training and within their area of professional competence.
Business sectors affected

20. Only independent healthcare organisations and individuals providing healthcare outside any arrangements funded by the NHS, who choose to implement independent prescribing will be affected. The introduction of independent prescribing by pharmacists is entirely voluntary. Only those pharmacists who wish to undertake the role will do so.

21. As at 31 March 2004 there were 10,462 community pharmacies in contract with Primary Care Trusts/Local Health Boards in England and Wales. Overall, in Great Britain at 31 December 2003, there were 12,492 pharmacy premises registered with the RPSGB, the vast majority of which were community pharmacies.

Compliance costs

22. Option 1: do nothing. This will have no additional costs for businesses, charities and voluntary organisations.

23. Options 2 to 7: This will not create any obligatory costs. If organisations decide they wish to take the opportunity they will have to pay to have their pharmacists trained and to gain and maintain accreditation of premises and individuals with the Royal Pharmaceutical Society of Great Britain or the Pharmaceutical Society of Northern Ireland. Based on training courses currently available for nurses, an appropriate training course may cost around £900 and accreditation may cost around £40. Current nurse prescribing courses run for 26 days plus 12 days of supervised practice. Increasingly, courses are being made available through distance learning which increases flexibility for those who wish to undertake them.

24. They will have to meet any set up costs such as creation of consultation space and ensuring adequate record keeping and communications systems are in place. Costs for this will vary, amongst other things, according to the business’s choice of supplier, design and specification. In many pharmacies these facilities will already be in place to deliver existing services so little if any additional expenditure will be needed. Even where they are introduced to enable independent prescribing, once in place, they will support other areas of the business. Pharmacies will need to ensure the trained pharmacists have sufficient time to undertake their
prescribing role and, while they do so, that there is appropriate supervision of the dispensary.

25. The businesses involved will already be subject to regulation so any activity flowing form this proposal is likely to add slightly to existing tasks rather than create new ones. None of these costs are mandatory. Independent prescribing is entirely voluntary so incurring the costs is a matter for the economic and professional judgement of the individual or business concerned.

26. Once qualified, pharmacists will need to maintain their skills and keep them up to date through continuing professional development. This is an existing requirement; prescribing would not alter this but would shape the content.

27. We would welcome views on the likely costs

Other costs

28. There will be no costs for society or the environment.

Consultation with small business

29. We have had informal discussions with a range of stakeholders including representatives of retail pharmacy including National Pharmaceutical Association, Company Chemists Association and the Guild of Healthcare Pharmacists. They have expressed no concerns about the costs of implementation as they understand that implementation is entirely voluntary based on their commercial and professional judgement. This is a development which the pharmacy profession welcomes.

30. The formal consultation document which this partial RIA accompanies asks for further views.

Competition assessment

31. The proposal was considered against the OFT’s competition filter. The response to the majority of the Questions was “no”. We therefore conclude that the proposal will not impact on the independent healthcare market.

Rural Proofing
32. Based on the criteria contained in The Countryside Agency’s toolkit for assessing the rural impact of policy proposals, no action is required to rural proof these possible changes. The proposals will not adversely affect access to medicines or pharmacist/GP services within rural communities. The proposals will increase choice and benefit those people in rural areas who have easier access to a pharmacy than to a GP. In many instances it will give them the option of attending either a pharmacy or a dispensing GP.

**Enforcement and Sanctions**

33. These proposals are voluntary so sanction would only apply where an organisation had participated voluntarily and then failed to operate within medicines legislation or within the rules of the regulatory bodies. The Medicines & Healthcare Products Regulatory Agency is responsible for enforcing medicines legislation. The Royal Pharmaceutical Society of Great Britain and the Pharmaceutical Society of Northern Ireland are responsible for matters of professional regulation.

**Monitoring and review**

34. The Department of Health is currently commissioning an evaluation of supplementary prescribing by nurses and pharmacists. Evaluation will continue to be an integral part of the non-medical prescribing programme.

**Consultation**

35. The groups with whom informal discussions have been held are listed in the annexes to the consultation document.

**Public Consultation**

36. This partial RIA accompanies the public consultation document.

**Summary and recommendation**

37. No specific option is recommended. Options 2 to 7 meet the Government’s objectives of safely improving patients’ access to medicines and maximising use of pharmacists’ professional skills.

**Declaration**
38. To be completed after the formal consultation is complete.
Organisations Contacted During Informal Consultation –
June to November 2004

British Medical Association
Royal College of Surgeons
Royal College of General Practitioners
Royal College of Physicians
Academy of Medical Royal Colleges

National Consumer Council
Consumers’ Association
Patients’ Forum
Action Against Medical Accidents
Patients’ Association
Long-Term Medical Conditions Alliance
Commission for Patient and Public Involvement

Royal Pharmaceutical Society of Great Britain
National Pharmaceutical Association
Pharmaceutical Services Negotiating Committee
Scottish Pharmaceutical General Council
National Prescribing Centre
Company Chemists Association
Guild of Healthcare Pharmacists
Pharmaceutical Society of Northern Ireland
Association of Pharmacy Technicians
Commission for Social Care Inspection

Community Practitioners’ and Health Visitors’ Association
Nursing and Midwifery Council
Royal College of Nursing
Royal College of Midwives
Unison
Community and District Nurses’ Association

Strategic Health Authority and Primary Care Trust Non-Medical
Prescribing Leads
MLX 321 Hard Copy Consultation List

NB: this list is not intended to be exhaustive. Copies of the consultation are also available from our website - www.mhra.gov.uk – and replies are welcome from all interested parties.

Action for Sick Children
Advisory Committee on Misuse of Drugs
Arthritis Care
Arts Therapies Advisory Group
All Party Pharmaceutical Group
Amicus
Association of British Cardiac Nurses
Association of Nurse Prescribing
Association for Palliative Medicine
Association for Residential Care
Association of Anaesthetists of Great Britain and Northern Ireland
Association of British Health Care Industries
Association of British Pharmaceutical Industries
Association of Independent Multiple Pharmacies
Association of Medical Microbiologists
Association of Surgeons of Great Britain and Ireland
British Association of Dermatologists
British Association for A&E Medicine
British Association of Pharmaceutical Physicians
British Association of Pharmaceutical Wholesalers
British Association of Prosthetists and Orthotists
British Cardiac Patients Association
British Contact Dermatitis Group
British Dental Association
British Dental Trade Association
British Diabetic Association
British Dietetic Association
British Generic Manufacturers Association
British Heart Foundation
British Institute of Regulatory Affairs
British and Irish Orthoptic Society
British Medical Association
British Oncological Association
British Pharmacological Society
British Society for Antimicrobial Chemotherapy
British Society of Gastroenterology
Carers National Association
Chartered Society of Physiotherapy
Chemist & Druggist
College of Health
College of Occupational Therapists
College of Optometrists
College of Pharmacy Practice
Community Practitioners and Health Visitors Association
Community Pharmacy Magazine
Company Chemists Association
Consumers Association
Co-operative Pharmacy Technical Panel
Counter Fraud & Security Management Services
Dental Defence Union

Dental Formulary Subcommittee of the Joint Formulary Committee
Dental Protection Ltd
Dispensing Doctors Association
Doctor Magazine
Drug & Therapeutics Bulletin
Drug Information Pharmacists Group
European Association of Hospital Pharmacists
Faculty of Pharmaceutical Medicine
General Dental Council
General Dental Practitioners Association.
General Medical Council
General Practitioners Committee
Guild of Healthcare Pharmacists
Health & Safety Executive
Healthcare Commission
Health Development Agency
Health Professions Council
Health Promotion England
Health Service Commissioner
Health Which?
Independent Healthcare Association
Joint Consultants Committee
Joint Formulary Committee
Joint Royal Colleges Ambulance Service Liaison Committee
Long Term Medical Conditions Alliance
Medical Defence Union
Medical Protection Society Ltd
Medical Research Council
MIMS Ltd
National Association of GP Co-operatives
National Consumer Council
National Care Standards Commission
National Patient Safety Agency
National Pharmaceutical Association
National Treatment Agency
Neonatal and Paediatric Pharmacists Group
Nursing and Midwifery Council
OTC Bulletin
Overseas Doctors Association in the UK Ltd
Paediatric Chief Pharmacists Group
Patients Association
Pharmaceutical Journal
Pharmaceutical Services Negotiating Committee
Prescription Pricing Authority
Primary Care Pharmacists Association
Proprietary Association of Great Britain
Public Health Laboratory Service
Registered Nursing Home Association
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of Midwives
Royal College of Nursing
Royal College of Obstetricians & Gynaecologists
Royal College of Ophthalmologists
Royal College of Paediatrics and Child Health
Royal College of Pathologists
Royal College of Physicians (London)
Royal College of Physicians & Surgeons of Glasgow
Royal College of Psychiatrists
Royal College of Radiologists
Royal College of Speech and Language Therapists
Royal College of Surgeons (England)
Royal College of Surgeons (Faculty of Dental Surgery)
Royal College of Surgeons of Edinburgh
Royal Colleges of Physicians : Faculty of Pharmaceutical Medicine
Royal Colleges of Physicians : Faculty of Public Health Medicine
Royal Pharmaceutical Society of Great Britain
Royal Society of Chemistry
Royal Society for the Promotion of Health
Scrip Ltd
Small Business Service
Social Audit
Society of Chiropodists and Podiatrists
Society and College of Radiographers
Society of Homoeopaths
Society of Pharmaceutical Medicine
Specialist Advisory Committee on Antimicrobial Resistance
St John Ambulance
UK Clinical Pharmacy Association
Unison
Annex E

Consultation Response Proforma

Please write or e-mail to:
Roy Drepaul, 16/139, Medicines and Healthcare Products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London, SW8 5NQ. E-mail: roy.drepaul@mhra.gsi.gov.uk

QUESTIONS FOR RESPONSE – a space is available below each question for your response

1. **QUESTION** We would welcome views on whether this definition is suitably robust and encompasses all situations in which pharmacists will need to prescribe. (para 13)

**RESPONSE**

2. **QUESTION** We would welcome views on the benefits to be gained form the introduction of independent prescribing by pharmacists. (para 20)

**RESPONSE**

3. **QUESTION** We would welcome views on whether different prescribing frameworks might apply to different work settings. What in your view are the key issues that should drive such a decision? (para 27)

**RESPONSE**

4. **QUESTION** We would welcome views on whether it is feasible and beneficial to make no change. (para 30)
5. **QUESTION**  We welcome your views on whether pharmacists should prescribe for certain conditions from a limited formulary. (para 33)

**RESPONSE**

6. **QUESTION**  We would welcome your views on the suitability of the formulary and list of conditions for pharmacist independent prescribing. Are there conditions or medicines that should be added or deleted and what are your recommendations? (para 34)

**RESPONSE**

7. **QUESTION**  We would welcome your views on whether pharmacists should prescribe for any condition from a limited formulary. Are there any conditions that should be excluded and what are your recommendations? (para 36)

**RESPONSE**

8. **QUESTION**  We would welcome your views on the suitability of the Nurse Prescribers Extended Formulary for pharmacist
independent prescribing. Are there medicines that should be added or deleted and what are your recommendations? (para 37)

RESPONSE

9. **QUESTION** We would welcome views on whether pharmacists should prescribe from the full British National Formulary for a specific set of conditions. In particular what specific conditions, over and above those currently treatable by extended nurse prescribers should be treated by independent prescriber pharmacists? (para 39)

RESPONSE

10. **QUESTION** We would welcome views on whether pharmacists should prescribe for any condition from the full British National Formulary. In particular, do you have any views on classes of drugs which you would consider inappropriate for prescribing by pharmacists? (para 41)

RESPONSE

11. **QUESTION** We would welcome views on whether different approach to independent prescribing by pharmacists should be adopted for different clinical settingsa mixed approach should be adopted to independent prescribing by pharmacists. (para 43)

RESPONSE
12. **QUESTION** We would welcome views on whether pharmacists should be able to prescribe any medicines from the BNF provided that a diagnosis has already been made by a GP or consultant, and from an agreed formulary where there is not access to a diagnosis. (para 45)

**RESPONSE**

13. **QUESTION** Which option would you favour overall and why? (para 46)

**RESPONSE**

14. **QUESTION** If we adopted any of options 3 to 7 this would mean that there were differences in the rules governing independent prescribing by pharmacists and nurses, ie pharmacist prescribing would not be restricted to particular conditions. Are there reasons why a different approach should be taken to independent prescribing by pharmacists and what are they? (para 47)

**RESPONSE**

15. **QUESTION** Should the same advice on the separation of prescribing and dispensing be given to pharmacist independent prescribers as is given to supplementary prescribers? Is this sufficient to ensure safety? Are there any other practical arrangements that could be made to improve this? (para 60)

**RESPONSE**
PLEASE USE THIS SPACE FOR ANY OTHER VIEWS YOU WISH TO EXPRESS ABOUT INDEPENDENT PRESCRIBING FOR PHARMACISTS

* My reply may be made freely available
* My reply is confidential
* My reply is partially confidential (please indicate clearly any confidential elements)

Signed..............................................................................................................................................

* Delete as appropriate