



Home Office

Drug Legislation Section

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Date 22 March 2007

Dear Sir/Madam

PUBLIC CONSULTATION – INDEPENDENT PRESCRIBING OF CONTROLLED DRUGS BY NURSE AND PHARMACIST INDEPENDENT PRESCRIBERS

Introduction

1. This letter seeks your views on the proposals to expand the range of Controlled Drugs that can be prescribed independently by Nurse Independent Prescribers and to enable Pharmacist Independent Prescribers to independently prescribe Controlled Drugs. It also seeks your views on whether nurse and pharmacist prescribers should be allowed to prescribe specific Schedule 2 drugs to addicts for the management of their addiction.

2. This consultation letter has been drawn up by the Home Office in consultation with the Department of Health (DH), as well as the Advisory Council on the Misuse of Drugs (ACMD). Following the close of the consultation, the ACMD will be asked to make a formal recommendation, in light of the responses, to Ministers. The Home Office have issued this letter, as any changes will require an amendment to the Misuse of Drugs Regulations 2001 and possibly the Misuse of Drugs (Supply to Addicts) Regulations 1997. Consequential amendments would be required to the medicines legislation, and these proposals have already been the subject of a DH/Medicines and Healthcare products Regulatory Agency (MHRA) consultation in early 2005.

3. This consultation is open for 12 weeks and responses should arrive no later than **Friday 15 June 2007**.

Current Position on Controlled Drugs

4. Nurse Independent Prescribers are currently able to prescribe 12 Controlled Drugs independently, including diamorphine and morphine, solely for specified medical conditions. These drugs and medical conditions are listed at **Annex A**.

5. Pharmacist Independent Prescribers are unable to prescribe any Controlled Drugs independently (though community pharmacists can sell Schedule 5 Controlled Drugs from a pharmacy).

6. Both nurse and pharmacist supplementary prescribers can prescribe Controlled Drugs under a Clinical Management Plan for a patient in partnership with a doctor.

Background

7. Nurse independent prescribing (formerly known as Extended Formulary Nurse Prescribing) was introduced in 2002. At that time, it revolved around a list of medicines and medical conditions, known as the Nurse Prescribers' Extended Formulary, from which nurses could prescribe if they had received the required training in prescribing. A limited number of 6 Controlled Drugs were first included in the Formulary in October 2003, with a further 6 Controlled Drugs being added subsequently.

8. In February 2005, the DH and MHRA consulted on the options for the future of independent prescribing by Nurse Independent Prescribers (MLX320) and Pharmacist Independent Prescribers (MLX321). A copy of the two consultations and the responses to them is available on the MHRA website at www.mhra.gov.uk under Publications.

9. On the close of those consultations, the then Committee on Safety of Medicines (now the Commission on Human Medicines (CHM)) recommended to DH Ministers that Nurse Independent Prescribers and Pharmacist Independent Prescribers should be able to prescribe any licensed medicine for any medical condition within their competence. Changes to medicines and NHS regulations followed, with effect from 1 May 2006. However, the restrictions around Controlled Drugs remain.

Reasons for change

10. The White paper *"Our health, our care, our say: a new direction for community services"* (2006) set out the Government's commitment to increased flexibility and responsiveness in health and social services. As one part of this policy, the Government is committed 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 healthcare professionals; and
- contribute to the introduction of more flexible team working across the NHS.

11. In recent years, both nursing and pharmacy practice and responsibilities have changed considerably. Nurses and pharmacists have taken on increased individual responsibility for patient care, including for one-off episodes of care, and many of them are running clinics. Over 9,000 nurses in England have qualified as Nurse Independent Prescribers, whilst 750 pharmacists (over 1,000 in Great Britain) have qualified as Pharmacist Supplementary Prescribers. Many are providing services to patients in fields such as substance misuse, palliative care and pain relief.

12. Controlled Drugs are subject to special legislative controls provided by the misuse of drugs legislation as they are considered sufficiently "dangerous or otherwise harmful", with the potential for diversion and misuse. However, this legislation is not intended to impede the legitimate use of Controlled Drugs where clinically appropriate, but rather to regulate and govern it for reasons of patient and public safety. Both the CHM and the ACMD have advised Government that there is no evidence that expanding the prescribing of Controlled Drugs to nurse and pharmacist independent prescribers will lead to increased diversion or misuse.

13. Legal controls as well as governance arrangements for Controlled Drugs will apply to any changes. These continue to be strengthened with the implementation of the Government Response - *Safer management of Controlled Drugs* - to The Fourth Report of The Shipman Inquiry. All prescribers and dispensers of Controlled Drugs will operate within these tighter arrangements across both the public and independent sectors in health and social care.

- Since January 2007, all healthcare organisations and independent hospitals in England are required to nominate an officer of sufficient seniority – an Accountable Officer - to ensure that the organisation has robust arrangements for the safe and

effective management of controlled drugs. Similar arrangements will be introduced in Scotland and Wales.

- A duty of collaboration on healthcare organisations and other local and national agencies, including professional regulatory bodies, police forces, the Healthcare Commission and the Commission for Social Care Inspection will enable them to share intelligence on Controlled Drugs issues.
- A series of amendments to the 2001 Regulations relating to prescribing and the audit trail have included the reduction in the validity period of a prescription for most Controlled Drugs to 28 days and the requirement for private health prescriptions for Schedules 1, 2 and 3 Controlled Drugs to be issued on a standard prescription form which includes the prescriber's unique identification number. This means that prescriptions for Controlled Drugs written privately will be monitored in the same way as Controlled Drugs prescribed in the NHS.

14. The current list of Controlled Drugs from which a Nurse Independent Prescriber can prescribe is set out in Regulation 6B of the Misuse of Drugs Regulations 2001 (the 2001 Regulations). Any additions to this list require legislative change, usually preceded by public consultation and consultation with the ACMD. Consequently, changes to the list are cumbersome and are unlikely to keep pace with desired NHS practice.

15. Subject to robust governance, monitoring and training arrangements being in place, it is the Government's position that prescribing by qualified nurse and pharmacist prescribers should be considered in the same way as prescribing by doctors. The changes in May 2006, referred to in para 9 above, now form the bulwark of DH policy on non-medical prescribing for nurses and pharmacists. The current inability of Pharmacist Independent Prescribers to prescribe independently any Controlled Drugs and Nurse Independent Prescribers to prescribe a very limited range independently is at odds with this, and is seen as a potential barrier to patient choice and local innovation in providing services for patients.

The principles underpinning the expansion of prescribing of Controlled Drugs by nurses and pharmacists

16. The DH has established the principles governing non-medical prescribing through previous consultations and discussions with key stakeholders. Both the CHM and the ACMD have adopted the following principles in their considerations:

- Patient safety must be paramount;
- Nurse and Pharmacist Independent Prescribers must prescribe within their competence/specialty;
- Training for Nurse and Pharmacist Independent Prescribers must be monitored, validated and quality assured, and include, as it does, the legal requirements of prescribing Controlled Drugs;
- Clinical governance arrangements must be fully in place for Nurse and Pharmacist Independent Prescribers;
- Communication between prescribers is vital and all prescribers must have access to the appropriate part of the patient's medical records;
- Prescribing and dispensing must always be separate for Controlled Drugs;
- Nurse and Pharmacist Independent Prescribers will normally be senior or experienced professionals, often working in specialist areas, and as such, will remain a relatively small cohort of the nursing and pharmacy workforce.

17. In order to ensure safe and effective prescribing practice, the requirement that Nurse and Pharmacist Independent Prescribers must only prescribe within their competence is central to the expansion of independent prescribing.

- The relevant professional and regulatory bodies – the Nursing and Midwifery Council (NMC) and the Royal Pharmaceutical Society of Great Britain (RPSGB) – place strict requirements on their registrants that they must only work within their competence and that they must maintain their competence levels. In respect of prescribing, the NMC has developed detailed standards, which nurse independent prescribers must

satisfy. The RPSGB has developed the outline curriculum for pharmacist prescribers and has strengthened its Code of Ethics for pharmacist prescribers.

- Strategic Health Authorities, Primary Care Trusts, NHS Trusts and other employing organisations must also take steps to ensure that nurses and pharmacists are competent to prescribe within their chosen therapeutic area and that prescribing by nurses and pharmacists is monitored in the same way as for doctors.
- To define and promote the relevant competencies to prescribe, the National Prescribing Centre (NPC) has developed a competency framework, available on its website at www.npc.nhs.uk. The framework establishes 3 areas of competence – the consultation (which includes competences in diagnosis), prescribing effectively and prescribing in context
- The NPC's competency framework is used to inform the curriculum development by most of the Higher Education Institutions, which offer training courses for nurse and pharmacist prescribers. Both the NMC and the RPSGB accredit the Higher Education Institutions to ensure that the courses are of the appropriate standard. Organisations that employ Nurse and Pharmacist prescribers should also use the competency framework as a Continuing Professional Development tool, to identify gaps in knowledge and take steps to meet that gap.

PROPOSAL FOR THE EXPANSION OF PRESCRIBING OF CONTROLLED DRUGS BY NURSE AND PHARMACIST INDEPENDENT PRESCRIBERS

18. In line with the Commission on Human Medicines' recommendation set out in para 9 and the views expressed by the ACMD (which remain subject to its further consideration in light of the responses), it is proposed that the 2001 Regulations should be amended to allow the independent prescribing of any Controlled Drug from Schedules 2, 3, 4, and 5 by Nurse Independent Prescribers and Pharmacist Independent Prescribers according to their competence.

If this proposal is adopted, it should be noted that Nurse and Pharmacist Independent Prescribers would still not be able to prescribe cocaine, diamorphine or dipipanone (Schedule 2 drugs) for addicts for the management of their addiction, unless further changes are made (see para 28-30 below).

19. We welcome views on this proposal. We also welcome views on the timing of the implementation of this proposal (see para 33 on Issues for Implementation below).

Alternative options

20. As alternatives to the proposals set out above, the following options were also considered by the ACMD but were not supported.

Option A : No Change

21. This would continue to allow Nurse Independent Prescribers to prescribe 12 Controlled Drugs from the specified list and medical conditions but there are signs that the list of Controlled Drugs and medical conditions is already becoming out-of-date and is not keeping pace with contemporary NHS practice. Consequently, access to the medicines needed by a patient would continue to be restricted and therefore patient care may be compromised.

22. As an alternative to the proposal above at para 18, we welcome views on this option.

Option B : Give Pharmacist Independent Prescribers the same powers to prescribe Controlled Drugs as Nurse Independent Prescribers under current arrangements

23. Whilst there is logic to this, it still does not address the need to keep up with contemporary NHS practice - raised in para 14 above.

24. As an alternative to the proposal above at para 18, we welcome views on this option.

Option C : Any licensed medicine in Schedule 4 and 5, together with the Schedule 2 and 3 Controlled Drugs already approved, plus methadone to treat substance misuse, should be prescribable by Nurse Independent Prescribers and Pharmacist Independent Prescribers -

25. This would make sense in that there would be no need for a list of specific Schedule 4 and 5 drugs to be kept up-to-date. It would still exclude some of the Schedule 2 and 3 drugs needed to care for patients - though it would include the six Schedule 2 and 3 CDs already approved, including diamorphine and morphine albeit only for certain medical conditions. Methadone would be added for substance misuse, which would assist treatment of patients suffering from addiction. Pharmacist Independent Prescribers would have the same prescribing powers for Controlled Drugs as Nurse Independent Prescribers. The ACMD's view was that the provision of prescribing powers by reference to schedules under the 2001 Regulations could cause uncertainty and may not aid safe prescribing.

Option D : Any licensed medicine from Schedule 4 and 5, together with the six Schedule 2 and 3 Controlled Drugs already approved plus methadone, but without restriction to the specified medical conditions, should be prescribable by Nurse Independent Prescribers and Pharmacist Independent Prescribers

26. By abandoning the specified medical conditions, the 2001 Regulations would in part mirror the changes made to medicines regulations for prescribing of drugs other than Controlled Drugs. This would also enable more flexible arrangements for the treatment of patients. It would still limit prescribing of Schedule 2 and 3 CDs to the six drugs already approved, but would add methadone, which would assist treatment of patients suffering from addiction. Pharmacist Independent Prescribers would have the same prescribing powers as Nurse Independent Prescribers. The ACMD's view was similar to that expressed in relation to Option C.

27. As alternatives to the proposals above at para. 18, we welcome views on Options C and D.

PRESCRIBING OF DIAMORPHINE, COCAINE OR DIPIPANONE FOR ADDICTS FOR THE MANAGEMENT OF ADDICTION

28. Under current legislation, diamorphine, cocaine or dipipanone can be prescribed for addicts for the management of their addiction but only by those doctors licensed by the Home Office, or by doctors who have been delegated this task under the express provisions of another doctor's licence. On most occasions when a licence is given to a non-addiction psychiatry specialist doctor (e.g. a general practitioner with additional training in addiction or an addiction psychiatry trainee), the licence is issued with a condition that the doctor must either not initiate prescribing, without first discussing the patient with an addiction psychiatrist who should also hold such a licence, or may only be issued such a licence once suitable clinical supervision arrangements have been established. Other conditions can be attached. Only a small number of licences for diamorphine have to date been issued to doctors; licences for cocaine and dipipanone are very rare.

29. We are **not** at present minded to take action to enable nurse and pharmacist prescribers to apply for a licence to treat addicts with these drugs in the same way as a general practitioner with additional training in addiction. We wish to give further consideration to the feasibility of such a change and to the effective monitoring of licensing

conditions, to ensure suitable highly specialised oversight of such prescribing in the event of such a change.

30. **However, we would nevertheless welcome views on whether the Misuse of Drugs (Supply to Addicts) Regulations 1997 should be amended to allow Nurse and Pharmacist Supplementary Prescribers¹ or Nurse and Pharmacist Independent Prescribers to prescribe diamorphine, (cocaine or dipipanone) for addicts for the management of addiction under Home Office licence.**

Impact of Legislation on Business

31. In 2005, the DH and MHRA prepared Regulatory Impact Assessments (RIA) that set out the overall effect of the expansion of Nurse Independent Prescribing and the introduction of Independent Prescribing by Pharmacists in the healthcare sector. The same issues raised in these RIAs also apply to the extension of nurse and pharmacist independent prescribing of Controlled Drugs. **The combined, updated RIA dated March 2006 is attached for information at Annex B.**

32. We welcome views from business, voluntary organisations and charities as to how they see the likely impact of the current proposals and whether they have identified and quantified any additional direct or indirect costs (recurring and non-recurring) that may arise if the proposals are implemented.

Issues for implementation

33. Subject to the consideration of responses, the formal recommendation of the ACMD and the agreement of Ministers, the earliest time for any legislation change will be late Summer 2007. As part of its final assessment both as to the proposal(s) and the timing of their introduction, the ACMD will consider the extent to which clinical governance arrangements are in place in respect of Nurse and Pharmacist Independent Prescribers. In view of the role to be played by the Accountable Officer in securing the safe and effective handling of Controlled Drugs, including prescribing, the ACMD will also consider the extent to which the role of the Accountable Officer has been embedded in England and the Devolved Administrations.

Application to England, Wales, Scotland and Northern Ireland

34. The proposed changes to the 2001 Regulations would have effect in England, Wales and Scotland.

35. Northern Ireland has its own Misuse of Drugs Regulations. The Department of Health, Social Services and Public Safety in Northern Ireland will be considering similar changes to their regulations. Northern Ireland correspondents are therefore asked to forward their comments to Karen.Savage@dhsspsni.gov.uk.

Circulation of Proposals

36. A copy of this letter and attachments is also available at www.homeoffice.gov.uk and there will be links to this consultation at the DH and MHRA websites. You should contact the address given below (para. 37) if you require a copy of this consultation paper in any other format, e.g. braille, large font, audio.

Consultation Responses

¹ The Department of Health/MHRA introduced "Supplementary Prescribing" in 2003. Supplementary Prescribing is defined as a voluntary prescribing partnership between an independent prescriber (a doctor) and a supplementary prescriber, to implement an agreed patient-specific Clinical Management Plan with the patient's agreement.

37. The Government welcomes your views on the proposals contained in this document. Please send written comments using the attached response form at Annex C to:

Chris Edwards
Drug Legislation Section
Drug Strategy Unit
Home Office
2 Marsham Street
LONDON SW1P 4DF

or by email to: **ConsultationNIPSandPIPS@homeoffice.gsi.gov.uk**

38. Comments must be received by Friday 15 June 2007.

39. A summary of the responses received will be published within 3 months of the closing date and will be made available on the Home Office website (www.homeoffice.gov.uk)

Responses: Confidentiality & Disclaimer

40. The information you send us may be passed to colleagues within the Home Office, other Government departments or related agencies. Furthermore, information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes. These are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004.

41. If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

42. Please ensure that your response is marked clearly if you wish your response and name to be kept confidential. Confidential responses will be included in any statistical summary of numbers of comments received and views expressed.

43. The Department will process your personal data in accordance with the DPA – in the majority of circumstances this will mean that your personal data will not be disclosed to third parties.

Cabinet Office Code of Practice on Consultation

44. This consultation follows the Cabinet Office Code of Practice on Consultation - the criteria for which are set below.

- Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.
- Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses.
- Ensure that your consultation is clear, concise and widely accessible.
- Give feedback regarding the responses received and how the consultation process influenced the policy.
- Monitor your department's effectiveness at consultation, including through the use of a designated consultation co-ordinator.

- Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.

The full code of practice is available at:

www.cabinet-office.gov.uk/regulation/Consultation

Consultation Coordinator

45. If you have any complaints or comments specifically about the consultation process only, you should contact the Home Office consultation co-ordinator Christopher Brain by email at: christopher.brain2@homeoffice.gsi.gov.uk

Alternatively, you may wish to write to:

Christopher Brain
Consultation Co-ordinator
Performance and Delivery Unit
Home Office
3rd Floor Seacole
2 Marsham Street
London
SW1P 4DF

Yours faithfully,

Angela Scrutton
Head of Drug Legislation
Drug Strategy Unit

Annex A

Nurse Independent Prescribers are able to prescribe independently the following list of Controlled Drugs for the medical conditions indicated:

Drug	Indication	Route of administration
Buprenorphine	Transdermal use in palliative care	Transdermal
Chlordiazepoxide hydrochloride	Treatment of initial or acute withdrawal symptoms caused by the withdrawal of alcohol from persons habituated to it.	Oral
Codeine phosphate	N/A	Oral
Co-phenotrope	N/A	Oral
Diamorphine hydrochloride	Use in palliative care, pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case post-operative pain relief	Oral or parenteral
Diazepam	Use in palliative care, treatment of initial or acute withdrawal symptoms caused by the withdrawal of alcohol from persons habituated to it, tonic-clonic seizures	Oral, parenteral or rectal
Dihydrocodeine tartrate	N/A	Oral
Fentanyl	Transdermal use in palliative care	Transdermal
Lorazepam	Use in palliative care, tonic-clonic seizures	Oral or parenteral
Midazolam	Use in palliative care, tonic-clonic seizures	Parenteral or buccal
Morphine hydrochloride	Use in palliative care, pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case post-operative pain relief.	Rectal
Morphine sulphate	Use in palliative care, pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case post-operative pain relief.	Oral, parenteral or rectal
Oxycodone hydrochloride	Use in palliative care	Oral or parenteral administration in palliative care

For the purposes of nurse independent prescribing, palliative care means the care of patients with advanced, progressive illness.

REGULATORY IMPACT ASSESSMENT

This RIA was prepared by the DH and MHRA for their consultation in 2005 on the general expansion of Nurse Independent Prescribing and the introduction of Independent Prescribing by Pharmacists in the healthcare sector. The RIA was updated in March 2006.

The options set out below refer to the proposals raised in that earlier consultation, and not the options referred to in the body of this consultation letter.

THE FUTURE OF THE NURSE PRESCRIBERS' EXTENDED FORMULARY AND THE INTRODUCTION OF INDEPENDENT PRESCRIBING BY PHARMACISTS:

Issue

1. The Government is committed to improving patients' access to NHS prescription medicines and making better use of professional skills, while freeing up time for GP appointments. This was set out in the NHS Plan July 2000 and the NHS Improvement Plan July 2004. As set out in paragraph 3, the NHS is not regarded as a "business, charity or voluntary organisation" for the purpose of this RIA but many of the same principles apply to healthcare services provided outside the NHS. The Government wants to ensure that patients both in the NHS and the independent healthcare sectors are treated in the same way with more access to professional skills and timely treatment.

The objective

2. The objective is to enhance patient care by improving access to medicines through an increased and more flexible use of nurse prescribing, and the introduction of independent prescribing by pharmacists, 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;
- free up the time of doctors to carry out other clinical work;
- contribute to the introduction of more flexible team working;
- maximise the benefits of fully utilising professional skills.

Scope of the RIA

3. The extent to which independent prescribing by nurses and pharmacists is adopted within national health organisations (NHS) 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. Health services provided outside the NHS and the service provided by community pharmacists, (excluding, for the purpose of this RIA, their NHS business operations), are regarded as businesses. However, independent prescribing by nurses and pharmacists does not create a new regulatory environment with which the businesses must comply at the outset. Whether businesses, employers and individual health professionals offer, or train to undertake, independent prescribing in the context of this RIA is entirely a voluntary decision for them based on their commercial and professional judgement.

Risk Assessment

4. In respect of nurses, the risks of not taking action could mean that patients may not be able to access easily the medicines they need, and the Nurse Prescribers' Extended Formulary may become more complicated for nurses to follow. Enabling nurses to prescribe any licensed medicine for any condition subject to clinical competence will not be at the expense of endangering public health. Nurse Independent Prescribers (the new title for those qualified as Extended Formulary Nurse Prescribers) will only be able to prescribe after completing the relevant training courses and being accredited by their regulatory body. Similar comments apply to the introduction of full prescribing responsibilities for pharmacists. Pharmacists currently prescribe as Supplementary Prescribers and the progression to

independent prescriber status is an extension of that responsibility. Pharmacist Independent Prescribers will only be able to prescribe as such once they have completed the relevant training courses and been accredited by their regulatory body. In order to maintain accreditation Nurse Independent Prescribers and Pharmacist Independent Prescribers will need to demonstrate that they take steps to keep their skills and knowledge up to date. As with all healthcare professionals, they should only work within their areas of competence.

Consultation and options

4. A wide range of interested parties throughout the UK were consulted in early 2005 on a variety of proposals for the expansion of extended formulary nurse prescribing and the introduction of prescribing by pharmacists. Detailed proposals were contained in MHRA/DH consultation letters MLX 320 and MLX 321. In summary, views were sought on:

Nurses	Pharmacists
-----	Option 1: no change (i.e., no independent prescribing by pharmacists)
Option A: no change - maintain the NPEF for specified medical conditions	Option 2: prescribing for certain conditions from a limited formulary
Option B: prescribing for any medical condition from a specific Formulary	Option 3: prescribing for any condition from a limited formulary
Option C: prescribing for specific medical conditions from a full Formulary	Option 4 : prescribing for specific conditions from a full formulary
Option D: prescribing for any medical condition from a full Formulary	Option 5 : prescribing for any condition from a full formulary
Option E: advanced practice nurses with a higher level of competencies	Option 6 : different approaches for the different clinical settings
-----	Option 7: a hybrid approach (between hospital, community and primary care based pharmacists)

5. Over 700 replies were received. Responses to the consultations closed at the end of May 2005. The results of consultation indicated that the majority of respondents, including both nurses' and pharmacists' representatives, felt that nurse prescribers and pharmacist prescribers should be able to prescribe any licensed medicine for any medical condition, where they are competent to do so. Doctors' organisations were more reticent, suggesting much more limited change. A full summary of the outcome of the consultation has been placed on the MHRA's website (www.mhra.gov.uk).

Assessment of options following consultation

6. The adoption of Option 1 (pharmacists) would not deliver any of the objectives outlined in paragraph 2 above. Options A and 2 would maintain the status quo for nurses, and introduce prescribing by pharmacists on the same basis, but this would restrict patients access to medicines and continue the practical difficulties in ensuring that a formulary for two different professions remains current. Nor would it make the best use of professional skills. Options B, C, 3 and 4 would introduce further formularies whether for medicines or medical conditions. Options D and 5 would enable qualified and accredited nurses and pharmacists to prescribe any licensed medicine for any medical condition subject to individual clinical competence. Options E, 6 and 7 would introduce advanced practitioner formularies with the same difficulties in maintaining currency.

7. Options D and 5 were regarded as the most effective. This would enable safe and effective practice which has advantages for both patients and healthcare staff (e.g. timely access to treatment for patients and a potential reduction in waiting times; maximising use of professional skills, and facilitating professional and career development).

Costs for business, charities, voluntary organisations and frontline services

8. Options D and 5 will not create any obligatory compliance costs for businesses. If independent healthcare sector organisations or community pharmacies decide they wish to take the opportunity to introduce nurse or pharmacist prescribing, they will have to pay to train and maintain the accreditation of individuals with the relevant professional body. These costs will include fees payable for training courses and in some cases, provision of locum cover. The cost of training to become a prescriber is estimated at around £1,000 per trainee. The consultation sought comments on likely costs but none were forthcoming. Where independent healthcare sector organisations decide to embark on the training of nurses or pharmacists to become independent prescribers we expect the long-term benefits to outweigh the costs. Nurse and pharmacist prescribers also need to ensure that they keep their skills up-to-date through Continuing Professional Development (CPD) but any costs associated with this are unlikely to be significantly different from those incurred as part of their professional role as nurses and pharmacist.

Other costs

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

Impact on small business

10. Implementation is voluntary; where independent healthcare sector organisations decide to embark on the training of nurses or pharmacists to become independent prescribers we expect the long-term benefits to outweigh the costs.

Equity and fairness

11. The Government wants to facilitate the continuing professional development of nurses and pharmacists and to use their professional skills more fully. The Government wants to ensure that patients, both in the NHS and in the independent healthcare sector, are treated similarly, with better access to medicines, professional skills and timely treatment.

Race equality issues

12. There are no specific race equality issues.

Rural issues

13. Expanding non-medical prescribing should improve access to medicines for patients in rural areas.

Competition Assessment

14. This proposal was considered against the Office of Fair Trading's competition Filter Test. The response to the majority of the questions was "no". We therefore conclude that the proposal will have little or no effect on the independent healthcare market. The results clearly show that the proposal would have no adverse effects on competition within the health care market. The proposal introduces no incentives or disincentives.

Enforcement and Sanctions

15. The proposals will be implemented through amendments to the Prescription Only Medicines (Human Use) Order 1997 and the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 which provides exemptions from the Medicines Act restrictions on sale and supply of medicines. There will also be consequential amendments to the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994, the Medicines (Child Safety) Regulations 2003 and the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005. As these proposals are voluntary, sanction would only apply where an organisation had participated voluntarily and then failed to operate within medicines legislation or within proper professional conduct. The Medicines and Healthcare products Regulatory Agency is responsible for enforcing medicines legislation on behalf of the Secretary of State. The Nursing and Midwifery Council is responsible for matters of professional regulation for nurses. The Royal Pharmaceutical Society of Great Britain and the Pharmaceutical Society of Northern Ireland have responsibility for matters of professional regulation for pharmacists.

Declaration

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed: Jane Kennedy

*Date: 23rd March 2006
Minister of State, Department of Health.*

Contacts:

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Annex C

CONSULTATION RESPONSE FORM

Please write or e-mail your response to:

**Chris Edwards,
Drug Legislation Section,
Drug Strategy Unit,
Home Office,
Floor 6, Peel Building,
2, Marsham St,
London SW1P 4DF**

E-mail: ConsultationNIPSandPIPS@homeoffice.gsi.gov.uk

Please ensure that your response is marked clearly if you wish your response and name to be kept confidential.

From : _____

Proposal

1. To amend the Misuse of Drugs Regulations 2001 to allow the independent prescribing of any Controlled Drugs from Schedules 2,3,4 and 5 of the 2001 Regulations by Nurse Independent Prescribers and Pharmacist Independent Prescribers. (Para. 18)

- A. I support the proposal.
- B. I have no comment to make on the proposal.
- C. My comments on the proposal are below/attached.

I have no comment/ the following comments (please delete as appropriate) on the alternative options A-D as set out in the consultation paper.

Option A (para. 21)

Option B (para. 23)

Option C (para. 25)

Option D (para. 26)

2. We also welcome views on whether the Misuse of Drugs (Supply to Addicts) Regulations 1997 should be amended to allow Nurse and Pharmacist Supplementary Prescribers or Nurse and Pharmacist Independent Prescribers to prescribe diamorphine, cocaine or dipipanone for addicts for the management of addiction under Home Office licence. (Para. 30)