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CONSULTATION ON OPTIONS FOR THE FUTURE OF INDEPENDENT PRESCRIBING BY EXTENDED FORMULARY NURSE PRESCRIBERS

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CONSULTATION ON OPTIONS FOR THE FUTURE OF INDEPENDENT PRESCRIBING BY EXTENDED FORMULARY NURSE PRESCRIBERS

A. PURPOSE OF THE DOCUMENT

Introduction

1. We are writing to consult you in accordance with section 129(6) of the Medicines Act 1968 about proposals for changes to independent prescribing by Extended Formulary nurse prescribers. This would be achieved by amendment to the Prescription Only Medicines (Human Use) Order 1997 (the "POM" Order) and NHS regulations.
2. The Department of Health and the Medicines and Healthcare Products Regulatory Agency (MHRA) have jointly produced this consultation document. It is also being circulated 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). This consultation looks at the Nurse Prescribers' Extended Formulary, which was introduced in 2002, and looks at options for the future of independent nurse prescribing.

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 Extended Formulary nurse prescribing and the arrangements for training within national health organisations are matters for each of the separate administrations. Nurse prescribing must comply with legislative requirements and those organisations outside the NHS that implement nurse prescribing should consider developing accompanying guidance similar to that which applies to the NHS.

Timing and Process

4. This consultation is open for 12 weeks and responses should arrive no later than **23 May 2005**.
5. A proforma is attached at Annex F, which you may find helpful to use in writing your response. As well as giving you the opportunity to give us your views on the specific questions raised by this consultation, it covers other issues raised by the consultation which you may wish to bear in mind in framing your response. We would welcome your views on these issues, as well as on the specific questions.
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 their advice will be conveyed to Ministers. Subject to the agreement of Ministers, we plan to implement any changes by Statutory Instrument by early 2006. Statutory Instruments are available from the Stationary Office and may also be viewed on their website <http://www.hmso.gov.uk>

B. NURSE PRESCRIBING: THE CURRENT CONTEXT

Background

7. Following piloting, the Department of Health introduced nurse prescribing for District Nurses and Health Visitors in England from 1998. The Nurse Prescribers' Formulary [for District Nurses and Health Visitors] enables them to prescribe from a limited formulary of appliances, dressings and some medicines for patients in the community. Over 28,000 nurses in England are now qualified to do so.
8. In 1999, the Review of Prescribing, Supply and Administration of Medicines chaired by Dr June Crown CBE recognised the potential for extending prescribing by nurses and others. Following public consultation, the Department of Health introduced a wider formulary for independent nurse prescribing in 2002: the Nurse Prescribers' Extended Formulary. Through changes to regulations and guidance, the Department also enabled a wider range of nurses (first level registered nurses) to train to become prescribers, and around 4,000 nurses in England have already qualified to do so.

Supplementary Prescribing

9. Over 3,000 nurses (and some pharmacists) have qualified to become "Supplementary Prescribers". Supplementary Prescribing is defined as a voluntary partnership between the independent prescriber (a doctor or dentist) and a supplementary prescriber to implement an agreed patient-specific Clinical Management Plan, with the patient's agreement. Such a partnership can be particularly helpful for patients with a long-term condition, e.g. asthma, diabetes or hypertension; a nurse or pharmacist may be well placed to prescribe for the patient's continuing care. Such arrangements should obviously continue, where it benefits the patient and the delivery of patient care. However, by its very nature, Supplementary Prescribing is not appropriate for prescribing for acute care or for one-off episodes of care.

Nurse Prescribers' Extended Formulary

10. The Nurse Prescribers' Extended Formulary (NPEF) is the focus of this consultation. The Extended Formulary is based on a fairly wide list of medical conditions that are judged appropriate by CSM and Ministers for nurse prescribing. A list of these conditions is at Annex A. The Extended Formulary now includes a list of around 180 Prescription Only Medicines (POMs), together with all Pharmacy and General Sales List medicines appropriate to those conditions - see Annex B.
11. Work to expand the NPEF has taken place throughout 2003 and 2004. Subject to Parliamentary approval, the Formulary and list of medical conditions will expand further in 2005, particularly for emergency care.
12. Nursing practice has changed in recent years and with 3 years experience of the Nurse Prescribers' Extended Formulary, the time is right to reconsider the basis on which the Extended Formulary was developed and look at options for the future of Extended Formulary nurse prescribing.
13. An outline of how the current arrangements work for prescribing training, accreditation, and access to the patient record is at Annex C.

Evaluation of Nurse Prescribing

14. The University of Southampton has recently completed an evaluation of nurse prescribing for the Department of Health.

It is clear from its conclusions that nurses and some doctors feel that the format of the Nurse Prescribers' Extended Formulary is in some cases restricting efficient NHS practice and benefit to patients. This consultation will offer a formal framework to consider views and suggestions, enabling those at the front-line to influence key policy decisions.

Rationale

15. It is government policy to extend prescribing responsibilities to non-medical professions 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.

16. Many nurses, particularly nurses with a higher level of competencies who are practising beyond their initial level of registration, are already running their own clinics. If they are trained as nurse prescribers, this will often benefit their patients and improve the services they offer, provided they can prescribe the medicines that patients need and are competent to do so.

Principles underpinning expansion of non-medical prescribing

17. Previous public consultations on nurse prescribing in 2000 and 2001, and discussions with consumer groups and a range of health professions, have led to broad agreement about the principles that should guide the extension of prescribing responsibilities. These same principles apply to the proposals outlined in this document concerning the expansion of Extended Formulary nurse prescribing:
 - patient safety must be paramount;
 - professionals will be expected to act within their professional code of conduct and only prescribe where they are fully competent to do so;
 - changes to prescribing arrangements will only occur, if 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;
- pharmacists and those charged with prescription reimbursement need to be able to identify easily those individuals entitled to prescribe;
- national policy on the 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.

Definition

18. The Review of Prescribing, Supply and Administration of Medicines 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. For the purpose of this consultation we suggest that an independent nurse prescriber can be defined as:-

“.....a practitioner (e.g. doctor, nurse, pharmacist) responsible for the assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical management required, including prescribing.”

19. **We would welcome views on whether this definition is suitably robust and encompasses the broad responsibilities of Extended Formulary nurse prescribers.**

Benefits of expanding Extended Formulary nurse prescribing

20. Patients benefit from a speedier and more accessible service in a range of ways. They can often consult a nurse more easily than a doctor or dentist. Nurse prescribers, who work in primary care can prescribe appropriate medicines, without having to wait for a doctor to sign a prescription.
21. Patients and the NHS benefit as some consultations are diverted to nurses. This means that doctors and other professionals can focus their time and energies more clearly on the areas and patients who most need their expertise.
22. Nurse prescribers 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.

Professional regulation

23. As with other NHS professionals, nurses are expected to work only within their level of professional competence and expertise, and to seek advice and make appropriate referrals to other professionals with different expertise. Nurses are accountable for their own actions, and need to be aware of the limits of their skills, knowledge and competence.

C. PROPOSALS FOR THE FUTURE DEVELOPMENT OF NURSE PRESCRIBING

24. There is a range of options for the future development of Extended Formulary nurse prescribing and these are outlined in greater detail in the following paragraphs.

Option A: No change - maintain a Nurse Prescribers' Extended Formulary for specified medical conditions

25. This continues the current arrangements whereby nurses are able to prescribe independently from a specific formulary of medicines for a certain range of medical conditions.
26. The Department of Health and the MHRA would continue to consider potential additions to (and deletions from) the medical conditions and medicines in the Extended Formulary, possibly on an annual or biennial basis. However, experience has shown that updating the Formulary is resource intensive, as it involves statutory public consultation, consideration by the Committee on Safety of Medicines (CSM) and changes to legislation; this process can take 12 to 17 months to finalise. More importantly, this timescale makes it virtually impossible to keep the Formulary up-to-date with innovations in care, so patient benefits are not realised as quickly as they could be.
27. **We would welcome views on the proposal to retain the current arrangements whereby nurses are able to prescribe from a specific formulary for a certain range of medical conditions.**

Option B: Prescribing for **any** medical condition from a specific Formulary

28. Under this option, nurse prescribers would be able to prescribe for any medical condition for which that medicine was appropriate (as per the British National Formulary) from a certain range of medicines, provided the management of that

condition was within their competence. There would be no specific list of medical conditions, but within this option, it would be possible to exclude certain conditions, if it was felt a nurse should never treat them.

29. This would expand Extended Formulary nurse prescribing by not restricting prescribing to particular medical conditions. It would allow more flexibility in service provision than the previous option, although the need to keep the Extended Formulary up-to-date would remain. The medicines available for independent nurse prescribing would be those listed in the Extended Formulary, together with any future additions.
30. **We would welcome views on this proposal. In particular, are there any medical conditions that you feel are inappropriate for inclusion?**

Option C: Prescribing for specific medical conditions from a **full** Formulary

31. Nurses would be able to prescribe independently any medicine from the British National Formulary, but only for a specific range of medical conditions. However, within this option it would be possible to restrict the prescribing of any medicines deemed inappropriate. This kind of restriction might also be agreed locally, for instance through a local drug and therapeutics committee or through a local trust Formulary.
32. **We would welcome views on this proposal. In particular, which specific medical conditions, over and above those currently treatable by Extended Formulary nurse prescribers (Annex A) would be appropriate for inclusion?**

Option D: Prescribing for **any** medical condition from a **full** Formulary

33. Extended Formulary nurse prescribers would be able to prescribe any medicine from the British National Formulary (BNF) for any medical condition. If this option were adopted, it could probably be modified to restrict the prescribing of any drugs deemed inappropriate. This kind of restriction might also be agreed locally, for instance through a local drug and therapeutics committee or through a local trust Formulary.
34. **We would welcome views on this proposal. In particular, do you have any views on classes of medicines that you would consider inappropriate for prescribing by Extended Formulary nurse prescribers?**

Option E: Advanced practice nurses with a higher level of competencies

35. A further option would be additional flexibility in prescribing on the attainment of "specialist nurse status". Nurses with a higher level of competencies who fulfilled particular criteria would be able to prescribe following training for any medical condition from the whole of the BNF, subject to their competence and expertise.
36. If this option were adopted, medicines legislation would define the boundaries of prescribing. Under this option, Extended Formulary nurse prescribers who did not have a higher level of competencies would still be limited to specific medical conditions and medicines. These conditions and a Formulary of medicines would still need to be kept up-to-date, on an annual or biennial basis.
37. **We would welcome views on this proposal. In particular, should advanced practice nurses with a higher level of competencies be able to prescribe for any medical condition within their competence, from the whole of the BNF?**

Controlled Drugs

38. The Government's response to the Shipman Inquiry agreed with the consensus view that nurses (and pharmacists) should be able to prescribe controlled drugs in their roles as a supplementary prescriber. It also agreed that in due course, the range of controlled drugs prescribable independently by Extended Formulary nurse prescribers would be expanded. This would apply to any of the options outlined above. However, as such expansion is subject to amendment of the Misuse of Drugs regulations, it is not possible to outline at this stage which controlled drugs may in future be prescribable by Extended Formulary nurse prescribers.
39. **We would however welcome views on whether any restrictions should be placed on prescribing of controlled drugs by nurses independently and, if so, what those restrictions should be.**
40. **Guidance**

The DH has issued detailed guidance on the implementation of the Nurse Prescribers' Extended Formulary

www.dh.gov.uk/PolicyandGuidance/MedicinesPharmacyandIndustry/Prescriptions/NursePrescribing/fs/en. This guidance will be updated in due course to reflect any changes as a result of this consultation. **We would welcome any suggestions for improving the guidance.**

Regulatory Impact Assessment

41. In our view, the benefits of expanding nurse prescribing greatly outweigh any disadvantages, which in any case are likely only to be the cost of training, which for the NHS is funded via Strategic Health Authorities, and possibly locum cover. A partial regulatory impact assessment is at **Annex D, which** attempts to quantify those costs. **Comments are sought on this assessment.**

Circulation of Proposals

42. This consultation letter is being sent in hard copy to those organisations listed. This list is not exhaustive. Copies of the consultation are also available from our websites - www.dh.gov.uk/consultations and www.mhra.gov.uk – and replies are welcome from all interested parties. The DH/MHRA will not enter into correspondence about the proposals contained in this consultation.
43. A form is attached for your reply at Annex F. Comments should be addressed to **Non-Medical Prescribing Section, Department of Health, MPI-CCE, 5/E/46, Quarry House, Quarry Hill, Leeds LS2 7UE**. Alternatively, they can be e-mailed to: **mb-np.consultation@dh.gsi.gov.uk to arrive no later than 23 May 2005**. Comments received after this date will not be taken into account.

Making copies of replies available to the public

44. The Department of Health will make publicly available copies of responses that it receives. Copies will be made available as soon as possible after the public consultation has ended. The Department will supply copies on request. An administrative charge, to cover the cost of photocopying and postage, may be applied.
45. We will assume that you are content for your reply to be made available in this way, *unless* you indicate that you wish all or part of your reply to be treated as confidential and excluded from this arrangement. If you are replying by email,

we will assume that your consent overrides any confidentiality disclaimer that is generated by your organisation's IT system, unless you specifically include a request to the contrary in the main text of your submission.

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Nurse Prescribers' Extended Formulary - list of medical conditions at February 2005. [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

Annex B

Nurse Prescribers' Extended Formulary - list of medicines at February 2005. [Note: subject to Parliamentary approval, we anticipate that further medicines, particularly for emergency care, will be added in Spring 2005]

Drug	Route of administration, use or pharmaceutical form
Aciclovir	External
Acrivastine	Oral
Adapalene	External
Alclometasone dipropionate	External
Alimemazine tartrate (trimeprazine tartrate)	Oral
Amitriptyline hydrochloride	Palliative care - oral
Amorolfine hydrochloride	External
Amoxicillin trihydrate	Oral
Aspirin	Oral
Azelaic acid	External
Azelastine hydrochloride	Ophthalmic, nasal
Azithromycin dihydrate	Oral
Baclofen	Palliative care - oral
Beclometasone dipropionate	External, nasal
Betamethasone sodium phosphate	Aural, nasal
Betamethasone valerate	External, rectal
Budesonide	Nasal
Carbamazepine	Palliative care - oral,rectal
Carbaryl	External
Carbenoxolone sodium	Mouthwash
Cetirizine hydrochloride	Oral
Chloramphenicol	Ophthalmic
Cimetidine	Oral
Cinchocaine hydrochloride	Rectal
Clavulanic Acid	Oral
Clindamycin phosphate	External, vaginal
Clobetasone butyrate	External
Clotrimazole	External
Codeine phosphate	Oral
Conjugated oestrogens (equine)	External
Co-phenotrope	Oral
Cyclizine	Palliative care - parenteral
Dantrolene sodium	Palliative care - oral
Dantron	Oral
Desogestrel	Oral
Desoximetasone	External

Drug	Route of administration, use or pharmaceutical form
Dexamethasone	Aural
Dexamethasone isonicotinate	Nasal
Diazepam	Palliative care – oral, parenteral and rectal
Diclofenac diethylammonium	External
Diclofenac potassium	Oral
Diclofenac sodium	Oral, rectal
Dihydrocodeine tartrate	Oral
Domperidone	Palliative care - oral and rectal
Domperidone maleate	Palliative care - oral
Doxycycline	Oral
Doxycycline hyclate	Oral
Econazole nitrate	External, vaginal
Emedastine	Ophthalmic
Erythromycin	External, oral
Erythromycin ethyl succinate	Oral
Erythromycin stearate	Oral
Estradiol	External
Estriol	External
Ethinylestradiol	Oral
Etonogesterel	Implant
Etyndiol diacetate	Oral
Famotidine	Oral
Felbinac	External
Fenticonazole nitrate	Vaginal
Fexofenadine hydrochloride	Oral
Flucloxacillin magnesium	Oral
Flucloxacillin sodium	Oral
Fluconazole	Oral
Fludroxycortide (flurandrenolone)	External
Flumazenil	Parenteral
Flumetasone pivalate	Aural
Flunisolide	Nasal
Fluocinolone acetonide	External
Fluocinonide	External
Fluocortolone hexanoate	External, rectal
Fluocortolone pivalate	External, rectal
Flurbiprofen	Lozenges
Fluticasone propionate	External, nasal
Fusidic acid	External
Gabapentin	Palliative care - oral
Gentamicin sulphate	Aural
Gestodene	Oral
Glucagon hydrochloride	Parenteral

Drug	Route of administration, use or pharmaceutical form
Glucose	Parenteral
Hydrocortisone	External including rectal
Hydrocortisone acetate	External including rectal
Hydrocortisone butyrate	External
Hydrocortisone sodium succinate	Lozenges
Hyoscine butylbromide	Palliative care – parenteral
Hyoscine hydrobromide	Palliative care – oral, parenteral
Ibuprofen	External, oral
Ibuprofen lysine	Oral
Imipramine hydrochloride	Palliative care - oral
Ipratropium bromide	Nasal
Isotretinoin	External
Ketoconazole	External
Ketoprofen	External
Levocabastine hydrochloride	Nasal and ophthalmic
Levomepromazine (methotrimeprazine) maleate	Palliative care - oral
Levomepromazine (methotrimeprazine) hydrochloride	Palliative care - parenteral
Levonorgestrel	Oral
Lidocaine hydrochloride	External, parenteral
Lithium succinate	External
Lodoxamide trometamol	Ophthalmic
Loperamide hydrochloride	Oral
Loratadine	Oral
Lorazepam	Palliative care – oral, parenteral
Lymecycline	Oral
Mebendazole	Oral
Medroxyprogesterone acetate	Injection
Mestranol	Oral
Metoclopramide hydrochloride	Palliative care - oral and parenteral
Metronidazole	Oral, external, vaginal, rectal
Metronidazole benzoate	Oral
Miconazole	Dental lacquer
Miconazole nitrate	External, vaginal
Midazolam	Palliative care - parenteral
Minocycline hydrochloride	Oral
Mizolastine	Oral
Mometasone furoate	External, nasal
Nedocromil sodium	Ophthalmic
Nefopam hydrochloride	Oral
Neomycin sulphate	Aural

Drug	Route of administration, use or pharmaceutical form
Neomycin undecenoate	Aural
Nitrofurantoin	Oral
Nizatidine	Oral
Norethisterone	Oral
Norethisterone acetate	Oral
Norethisterone enanthate	Parenteral
Norgestimate	Oral
Norgestrel	Oral
Nortriptyline hydrochloride	Palliative care - oral
Nystatin	External, local mouth treatment, vaginal
Oxytetracycline dihydrate	Oral
Paracetamol	Oral
Penciclovir	External
Piroxicam	External
Prednisolone	Oral
Prednisolone hexanoate	Rectal
Prednisolone sodium phosphate	Aural, Oral
Ranitidine hydrochloride	Oral
Salbutamol sulphate	Inhalation
Silver sulphadiazine	External
Sodium cromoglicate	Ophthalmic
Sodium fusidate	External
Streptodornase	External
Streptokinase	External
Sulconazole nitrate	External
Terbinafine hydrochloride	External
Terbutaline sulphate	Inhalation
Tetracycline hydrochloride	External, oral
Tretinoin	External
Triamcinolone acetonide	Aural, external, nasal, oral paste
Trimethoprim	Oral
Tuberculin PPD	Injection
Vaccine, Adsorbed Diphtheria	Injection
Vaccine, Adsorbed Diphtheria and Tetanus	Injection
Vaccine, Adsorbed Diphtheria and Tetanus for Adults and Adolescents	Injection
Vaccine, Adsorbed Diphtheria for Adults And Adolescents	Injection
Vaccine, Adsorbed Diphtheria, Tetanus and Pertussis	Injection

Drug	Route of administration, use or pharmaceutical form
Vaccine, Adsorbed Diphtheria, Tetanus Toxoid and Pertussis (Acellular Component)	Injection
Vaccine, BCG	Injection
Vaccine, BCG Percutaneous	Injection
Vaccine, Haemophilus Influenzae Type B (Hib)	Injection
Vaccine, Haemophilus Influenzae Type B (Hib) with Diphtheria, Tetanus and Pertussis	Injection
Vaccine, Haemophilus Influenzae Type B (Hib), Diphtheria, Tetanus and Acellular Pertussis	Injection
Vaccine, Hepatitis A	Injection
Vaccine, Hepatitis A with Typhoid	Injection
Vaccine, Hepatitis A, Inactivated, with Recombinant (DNA) Hepatitis B	Injection
Vaccine, Hepatitis B	Injection
Vaccine, Influenza	Injection
Vaccine, Live Measles, Mumps and Rubella (MMR)	Injection
Vaccine, Meningococcal Group C Conjugate	Injection
Vaccine, Meningococcal Polysaccharide A and C	Injection
Vaccine, Pneumococcal	Injection
Vaccine, Poliomyelitis, Live (Oral)	Oral
Vaccine, Rubella, Live	Injection
Vaccine, Tetanus, Adsorbed	Injection
Vaccine, Typhoid, Live Attenuated (Oral)	Oral
Vaccine, Typhoid, Polysaccharide	Injection
Water for Injections	Parenteral

How the Current System Works.

(i) Who can train to prescribe?

SHA Workforce Development Directorates fund and commission training for prescribing in the NHS. Employers identify who needs to be trained, based on service need and individual capability. Nurses 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 of prescribing.

(ii) Commissioning Prescribing Services

PCTs are responsible for commissioning prescribing services in primary care and in the community. In doing so, they must have regard to the needs of their population, safety issues – especially adequate access to the patient record (see below) - and resource consequences.

PCTs, NHS Trusts and SHA Workforce Development Directorates should ensure that the therapeutic area in which the nurse will be prescribing is agreed, before s/he attending the prescribing training course.

(iii) Training & Accreditation

The Nursing and Midwifery Council (NMC) has agreed the standards for an outline curriculum for nurses to train as nurse prescribers. Higher Education Institutions devise courses to meet that curriculum and apply for accreditation to the NMC. Employers need to have arrangements in place to make sure that they are satisfied that individual nurses have the necessary clinical knowledge and skills in differential diagnosis, as well as prescribing skills.

Once nurses have qualified to prescribe, an entry is placed on the NMC register against the nurse's name to show that they are qualified. Prescribing becomes part of an individual's requirements for Continuing Professional Development and s/he is expected to show that s/he is maintaining skills and keeping them up-to-date.

(iv) Ensuring Safety

Access to the patient record

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 information they receive about the patient and any interventions they make, so that other professionals involved also have the full information they need to treat patients safely.

Partial Regulatory Impact Assessment

INDEPENDENT PRESCRIBING BY EXTENDED FORMULARY NURSE PRESCRIBERS AND AMENDMENTS TO THE PRESCRIPTION ONLY MEDICINES (HUMAN USE) ORDER 1997 AND NHS REGULATIONS

Issue

1. The Government is committed to improving patients' access to NHS prescription medicines and making better use of nurses' 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.

The objective

2. To enhance patient care by improving access to medicines through an increased and more flexible use of nurse prescribing 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 across the NHS.
3. 4,000 nurses in England have already qualified and registered as nurse prescribers to prescribe from the Nurse Prescribers' Extended Formulary. The Extended Formulary covers 80 medical conditions and 180 Prescription Only Medicines, together with all Pharmacy and General sales List medicines to treat these conditions. The consultation proposes options for widening nurse prescribing in a more systematic way.
4. Further information is in the main body of this consultation document.

Risk Assessment

5. 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. In addition, the Government

- Advanced practice nurses with a higher level of competencies

12. Each of the four options (B to E) would enable safe and effective practice to operate which has advantages for both patients and healthcare staff (e.g. timely access to treatment for patients and a potential reduction in NHS waiting times; maximising use of nurses' professional skills, and facilitating professional and career development). Nurses will only be able to prescribe after appropriate professional training, and should prescribe only within their own competencies, thus protecting patient safety. Patients will benefit from a speedier and more accessible service in a range of ways. They can often consult a nurse more easily than a doctor or dentist. Nurse prescribers who work in primary care will be able to prescribe an appropriate medicine, without having to wait for a doctor to sign a prescription. Patients and the NHS will benefit, if a patient can be treated more quickly. This means that doctors and other professionals can focus their time and energies on the areas and patients who most need their expertise. Nurse prescribers 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.

Costs for business, charities, voluntary organisations and frontline services

Business sectors affected

13. The independent healthcare sector that provides healthcare outside the NHS will only be affected, if it chooses to adopt, implement and expand Extended Formulary nurse prescribing.

Compliance costs

14. Option A – Do nothing. This will have no additional costs for businesses, charities, voluntary organisations and frontline services.

15. Options B-E - Amend medicines regulations and NHS regulations as proposed in the consultation, to widen Extended Formulary nurse prescribing. This will not create any obligatory compliance costs. If private sector organisations decide they wish to take the opportunity, they will have to pay to train and maintain the accreditation of individuals with the Nursing and Midwifery Council; this will include fees payable for training courses and in some cases, provision of locum

cover. Prescribing training courses are around 26 days, plus 12 days supervised practice with a doctor. Some Higher Education Institutions offer some of the training via distance learning. We estimate the cost of a prescribing training course place is around £850 per nurse. Strategic Health Authority Workforce Development Directorates commission and fund the training courses for NHS employees. Employers will also need to ensure that the nurse trained to prescribe has sufficient opportunity to undertake their prescribing role.

16. Options B to E do not create a new regulatory environment for businesses, as nurse prescribing is not new and training nurse prescribers is entirely a voluntary decision, to be taken in the light of benefits to their organisation, to patients and to the health professionals employed by those businesses. Once qualified as a nurse prescriber, the Nursing and Midwifery Council registers the nurse as a prescriber at a cost of £25 per nurse. If the scope of Extended Formulary nurse prescribing is widened, we expect the long-term benefits to outweigh the costs.

17. Nurse prescribers also need to ensure that they keep their skills up-to-date through Continuing Professional Development (CPD).

18. After qualification, there should be no significant additional costs to the NHS, apart from the need for CPD. Nurse prescribers will generally be prescribing medicines as a substitute for a doctor.

19. We would welcome views on the likely costs.

Other costs

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

Impact on small business

21. Implementation is voluntary. The formal consultation document, which this partial RIA accompanies, asks for further views.

Equity and fairness

22. The Government wants to facilitate the continuing professional development of nurses and to use their professional skills more fully, by continuing to widen the scope of Extended Formulary nurse prescribing. This will ensure better use of professional skills and more timely access to

treatment by patients. 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

23. There are no specific race equality issues.

Rural issues

24. Widening nurse prescribing should improve access to medicines for patients in rural areas.

Competition Assessment

25. 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

26. 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 proper professional conduct. The Medicines and Healthcare products Regulatory Agency is responsible for enforcing medicines legislation. The Nursing and Midwifery Council is responsible for matters of professional regulation.

Monitoring and Review

27. The Department of Health has commissioned an evaluation of independent nurse prescribing, which indicates that the range of conditions and medicines in the Nurse Prescribers' Extended Formulary has imposed limits on nurse prescribing. A summary of this evaluation is likely to be published later this year.

Consultation

28. Public Consultation – This partial RIA accompanies the public consultation document.

Summary and Recommendation

29. No specific option is recommended. Options B to E meet the Government's objectives of improving patients' access to medicines and maximising use of nurses' professional skills.

Declaration

30. To be completed after the formal consultation is complete.

Department of Health
February 2005

Hard Copy Consultation List

NB This list is not intended to be exhaustive. Copies of this consultation are also available from our websites – www.dh.gov.uk/consultations and www.mhra.gov.uk – and replies are welcome from all interested parties.

Action for Sick Children
Advisory Committee on Misuse of Drugs
Arthritis Care
All Party Pharmaceutical Group
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 Perinatal Medicine
British Association of Pharmaceutical Physicians
British Association of Pharmaceutical Wholesalers
British Cardiac Patients Association
British College of Optometrists
British Contact Dermatitis Group
British Dental Association
British Dental Trade Association
British Dermatological Nursing Group
British Diabetic Association
British Dietetic Association
British Generic Manufacturers Association
British Heart Foundation
British Institute of Regulatory Affairs
British Medical Association
British Oncological Association
British Pharmacological Society
British Society for Antimicrobial Chemotherapy
British Society of Gastroenterology
Carers National Association
Chemist & Druggist

College of Health
College of Pharmacy Practice
Community Practitioners and Health Visitors Association
Community Pharmacy Magazine
Company Chemists Association
Consumers Association
Co-operative Pharmacy Technical Panel
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
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 Psychiatrists
Royal College of Radiologists
Royal College of Surgeons (England)
Royal College of Surgeons (Faculty of Dental Surgery)
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 Homoeopaths
Society of Pharmaceutical Medicine
Specialist Advisory Committee on Antimicrobial Resistance
St John Ambulance
UK Clinical Pharmacy Association
Unison

**Consultation Response - please e-mail to mb-np.consultation@dh.gsi.gov.uk
Alternatively, if not possible, send by hard copy by 23 May to:**

Non-Medical Prescribing Section
Department of Health
Room 5/E/46
Quarry House
Quarry Hill
LEEDS LS2 7UE

From: _____

**CONSULTATION LETTER: OPTIONS FOR THE FUTURE OF
INDEPENDENT PRESCRIBING BY EXTENDED FORMULARY NURSE
PRESCRIBERS**

I have the following views on:

- **Definition of independent nurse prescriber** (paras 18 to 19)

- **Options for Future Development of Nurse Prescribing**

Option A: Maintain current arrangements- (paras 25-27)

Option B: Prescribing for any medical condition from a specific
Formulary - (paras 28 to 30)

Option C: Prescribing for specific medical conditions from a full
Formulary - (paras 31-32)

Option D: Prescribing for any medical condition from a full
Formulary - (paras 33-34)

Option E: Advanced practice nurses with higher competencies
(paras 35-37)

- **Prescribing of controlled drugs** (paras 38-39)
- **Guidance** - para 40
- **Regulatory Impact Assessment** - para 41

My preferred Option is

** My reply may be made freely available.*

** My reply is confidential.*

** My reply is partially confidential (indicate clearly in the text any confidential elements)*

Signed: _____

** Delete as appropriate*