EXPLANATORY MEMORANDUM TO

THE MEDICINES (SALE OR SUPPLY) (MISCELLANEOUS AMENDMENTS) REGULATIONS

2006 No. 914

1. This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency (MHRA), part of the Department of Health, and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. **Description**

2.1 These Regulations amend the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 which provides exemptions from the Medicines Act restrictions on sale and supply of medicines. They also make 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. Related statutory instruments are the Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006, the National Health Service (Miscellaneous Amendments Relating to Independent Prescribing) Regulations 2006 and the Nurses and Midwives (Parts of and Entries in the Register) Amendment Order of Council 2006.

3. **Matters of special interest to the Joint Committee on Statutory Instruments**

3.1 The SI is due to come into force on 1 May.

4. **Legislative Background**

4.1 These Regulations make further amendments to the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 which provides exemptions from the Medicines Act restrictions on sale and supply of medicines for human use. In particular, that prescription only (POM) and Pharmacy (P) medicines may only be sold or supplied on registered pharmacy premises by or under the supervision of a pharmacist (section 52 of the Act).

4.2 These Regulations remove the definitions of “district nurse/health visitor prescriber”, “Extended Formulary”, and “extended formulary nurse prescriber”. New definitions for “nurse independent prescriber”, “pharmacist independent prescriber” and “community practitioner nurse prescriber” are added, with appropriate references to the

annotations in the professional registers. Consequential amendments are made to the definition of "health prescription".

4.3 These Regulations also amend Schedule 2 of the 1980 Regulations so that particulars of nurse independent prescribers, pharmacist independent prescribers and community practitioner nurse prescribers, must be included in pharmacy records (pursuant to regulation 6(1)).

4.4 These Regulations also amend the Medicines (Child Safety) Regulations ("the Child Safety Regulations"), which in particular impose requirements relating to the packaging of certain medicinal products, so that the requirements do not apply to the retail sale, or supply corresponding to retail sale, of a product by a pharmacy, where that sale or supply is in accordance with a prescription given by a pharmacist independent prescriber or nurse independent prescriber.

4.5 Consequential amendments are also made 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 to reflect amendments made by the Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 to the professional register maintained by the Nursing and Midwifery Council. In particular, changes have been made to the definition of "registered nurse" and "supplementary prescriber".

5. **Extent**

5.1 This instrument applies to all of the United Kingdom.

6. **European Convention on Human Rights**

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. **Policy Background**

7.1 The changes relating to prescribing and sale and supply of medicines form part of the Government's policy of modernising the NHS. They enable appropriately trained healthcare professionals to prescribe, sell or supply medicines in the interests of improving patient care by appropriate use of professional skills.

7.2 The proposed amendments to expand nurse prescribing and to introduce independent prescribing by pharmacists were subject to public consultation and advice to Ministers by the then Committee on Safety of Medicines. Detailed analyses of the outcome of the two public consultation exercises have been published on the MHRA website: www.mhra.gov.uk. In both cases there was general support for the proposals although doctors' organisations were more reticent, suggesting much more limited change.

8. **Impact**

8.1 A Regulatory Impact Assessment is attached to this memorandum. The proposals do not impose a cost compliance on business, charities or voluntary bodies. It will be for those providing health care services outside the NHS to decide whether they wish to implement independent prescribing by nurses or pharmacists. However if they wish to do so, there will be some costs associated with, for example, training. The Regulatory Impact Assessment, which also covers associated changes made by the Medicines for Human Use (Prescribing)(Miscellaneous Amendments) Order 2006, has been prepared on that basis.

8.2 The impact on the public sector is principally to benefit patient care, by providing improved access to the medicines that patients need.

9. **Contact**

9.1 Anne Thyer at the MHRA tel: 020 70842642 or e-mail: anne.thyer@mhra.gsi.gov.uk can answer any queries regarding the instrument.

REGULATORY IMPACT ASSESSMENT

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 (ie, 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. The results of consultation indicated that the majority of respondees, 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.

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