

**EXPLANATORY MEMORANDUM TO THE  
NHS (PHARMACEUTICAL SERVICES) REGULATIONS 2005**

**2005 No. 641**

1. This explanatory memorandum has been prepared by the Secretary of State 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 The Statutory Instrument consolidates and amends the NHS (Pharmaceutical Services) Regulations 1992 and subsequent amendments.
3. **Matters of special interest to the Joint Committee on Statutory Instruments**
  - 3.1 None
4. **Legislative Background**
  - 4.1 The Instrument is being made under Sections 41, 42, 43, 43ZA, 49F, 49I, 49N, 49O, 49P and 49Q of the National Health Service Act 1977 as amended. It replaces the 1992 Regulations as amended to achieve three related policy objectives:
    - the introduction from 1 April 2005 of a new contractual framework for NHS community pharmacy services;
    - the implementation of the Government response for England to the Office of Fair Trading (OFT) report *The control of entry regulations and community pharmacy services in the UK*; and
    - the introduction of requirements under the Health and Social Care Act 2001, which amended the National Health Services Act 1977, for companies, their directors and superintendent pharmacists to make declarations as to their suitability to provide pharmaceutical services (known as “fitness to practice”).
5. **Extent**
  - 5.1 This instrument applies to England. Responsibility for the provision of NHS pharmaceutical services is devolved to the administrations in Scotland, Wales and Northern Ireland.

## **6. European Convention on Human Rights**

6.1 Not applicable

## **7. Policy background**

### **New contractual framework**

- 7.1 The Department reached agreement in early autumn 2004 on a new NHS pharmacy contractual framework, for England, with the Pharmaceutical Services Negotiating Committee (PSNC) and the NHS Confederation. A new framework is needed to be more flexible and to better reflect the expanded range of services which NHS primary care trusts (PCTs) wish community pharmacies to provide to meet local patients' needs and priorities. It also switches the emphasis of reward from volume and quantity of medicines dispensed to the quality and professionalism of the services provided.
- 7.2 In future, NHS pharmacies will provide three tiers of services – nationally agreed essential and advanced services and local enhanced services determined by the local PCT. NHS pharmacy contractors voted in favour of this package in November 2004 and the framework is to go live from 1 April 2005. The agreement applies to England and Wales. The National Assembly for Wales is responsible for implementation of the agreement in Wales.

### **The Government response to the OFT report**

- 7.3 Following its response in July 2003 to the OFT's report *The control of entry regulations and retail pharmacy services in the UK*, the Government announced on 18 August 2004 plans to implement a balanced package of measures to reform and modernise the NHS regulations which govern pharmacies in England. The Minister of State for Health, Rosie Winterton MP, made a Written Ministerial Statement to the House of Commons on 7 September 2004 (*Official Record Cols 98 – 101 WS*).
- 7.4 Currently, NHS PCTs in England assess applications under the National Health Service (Pharmaceutical Services) Regulations 1992 (as amended) and grant only if it is necessary or desirable for a new pharmacy to dispense NHS prescriptions in order to secure adequate services in a particular neighbourhood. Known as “control of entry” interested parties, including local pharmacists and pharmacy and GP representative bodies, are invited to give views on applications. Decisions are appealable. The system only controls a pharmacy's right to dispense NHS prescriptions – not whether a pharmacy can set up.
- 7.5 The current system does not encourage competition, innovation or new entry. With the reforms, more pharmacies will be able to offer NHS services where people live, work, shop and travel but essential access to pharmacy services in, for example, deprived and rural areas will be safeguarded. The reforms are to be implemented alongside the new contractual framework and apply only to England. The opportunity has been taken to implement a number of measures agreed by the Pharmaceutical Services Negotiating Committee, the General Practitioners' Committee of the British Medical Association and the Dispensing Doctors' Association to reform and

modernise the special arrangements which govern the provision of pharmaceutical services in rural areas.

### **“Fitness to practice” procedures**

- 7.6 These procedures mirror measures which began in November 2001 for GPs, dentists and ophthalmic opticians who provide NHS primary care services. Derived from the Health and Social Care Act 2001, and known as “main” or “provider” lists, they are essentially a range of checks and safeguards to help ensure providers of NHS pharmaceutical services are suitable and fit to provide such services to patients. They are more complex for pharmacy than other contractor groups because of the control of entry system. However these are necessary if PCTs are to take effective action, for example, in cases of serious crime. They will apply to companies providing pharmaceutical services (usually termed “bodies corporate”) and the directors of such companies and superintendent pharmacists, who are required to be appointed by the Medicines Act 1968 where a company provides pharmaceutical services, but who might not be directors.

### **Consultation**

- 7.7 The Department consulted on the proposals to introduce the fitness to practice regime in 2002 and to reform the control of entry system in autumn 2003. A summary of responses to the latter consultation is available on the Department’s website. The PSNC held a ballot of pharmacy contractors in 2004 on the new contractual framework with 92% of those who responded supporting the proposals. The Department most recently consulted the representative bodies for community pharmacy, primary medical services and appliance contractors on the draft Regulations. Having addressed their concerns, they are content with the final regulations.

## **8. Impact**

- 8.1 A Regulatory Impact Assessment is attached to this memorandum. This summarises the potential burdens on business and the public sector.
- 8.2 The impact on the public sector from implementation of these requirements is difficult to quantify, but has been estimated at a total cost of £10.4m annually, from increased entry to the community pharmacy market (£10m) and the requirements for PCTs to check information about “fitness to practice” (circa £0.4m). These will be offset by improved procedures governing the control of entry system and economies of scale in relation to fitness to practice.
- 8.3 The potential burden on business of the “fitness to practice” regime is estimated at £0.56m, comprising a one off cost of about £0.54m for existing contractors and £12,000 for new pharmacy entrants (assuming 100 such new entrants).
- 8.4 The Minister of State has concluded that the potential benefits from a more competitive market and from improved arrangements to maintain patient safety outweigh the potential costs.

## **9. Contact**

Peter Dunlevy  
Department of Health  
517 Eileen House  
80 – 94 Newington Causeway  
London SE1 6EF

Telephone number 0207 972 2881

e-mail: [peter.dunlevy@dh.gsi.gov.uk](mailto:peter.dunlevy@dh.gsi.gov.uk)