

**EXPLANATORY MEMORANDUM TO
THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES)
(AMENDMENT) REGULATIONS 2008**

2008 No. 683

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.
2. **Description**
 - 2.1 This Instrument amends the NHS (Pharmaceutical Services) Regulations 2005 – SI 2005/641 (“the 2005 Regulations”). The 2005 Regulations govern the provision of pharmaceutical services in England under Part 7 Chapter 1 of the National Health Service Act 2006
3. **Matters of special interest to the Joint Committee on Statutory Instruments**
 - 3.1 None
4. **Legislative Background**
 - 4.1 The 2005 Regulations govern the right to provide NHS pharmaceutical services. They contain a number of related matters such as the way in which community pharmacies are remunerated and their contractual requirements, known as Terms of Service. These Terms of Service are set out in Schedule 1 to the Regulations.
5. **Extent**
 - 5.1 This instrument applies to England.
 - 5.2 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 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 2005 Regulations provided the legislative basis for a new contractual framework for community pharmacies which provide NHS pharmaceutical services. They came into effect from 1 April 2005 following negotiations and agreement between the Department, the NHS Confederation which represented the interests of primary care trusts and the PSNC.
 - 7.2 This Instrument contains the following amendments to the 2005 Regulations:
 - 7.2.1 The ability of the Secretary of State to require pharmaceutical contractors to produce evidence of financial information regarding

their transactions from wholesalers for the drugs and other products they supply against NHS prescriptions. The effect is that the Secretary of State may, if necessary, rely on this provision to request information in order more accurately to calculate their remuneration against overall settlements agreed annually with the Pharmaceutical Services Negotiating Committee (PSNC), their representative organisation. This reinstates a previous provision that was repealed in April 2007 under SI 2007/674. That Statutory Instrument substituted Regulation 56 of the 2005 Regulations because of the change in the legislative basis upon which determinations relating to the remuneration of pharmaceutical services are made, following the consolidation of NHS legislative provisions under the NHS Act 2006. The substituted regulation 56 makes provisions relating to the determination of remuneration for persons providing pharmaceutical services by the determining authorities.

- 7.2.2 As part of the new community pharmacy contractual framework, clinical governance requirements were introduced from April 2005 which include a requirement to produce and make available a pharmacy practice leaflet giving patients information about the pharmacy. The amendment allows the Secretary of State for Health to specify the information that should be contained within the leaflet to ensure consistency and prevent pharmacy contractors from advertising non-NHS services or products.
- 7.2.3 The 2005 Regulations already contain provision to prevent pharmaceutical contractors offering inducements to patients for having NHS prescriptions dispensed at a particular contractor. An amendment extends this provision to include electronic as well as non-electronic NHS prescriptions.
- 7.2.4 Schedule 4 to the 2005 Regulations sets out information to be provided with applications, including from companies and their individual directors and superintendent pharmacist (a requirement of Section 71 of the Medicines Act 1968) regarding their fitness to practise. An amendment will require all companies to identify their superintendent pharmacist who must provide relevant information at the time of the application.

Consultation

- 7.3 We have worked closely with the PSNC on all these amendments and shared drafts of the Regulations with them. They have confirmed they are content with the amendments.

Guidance

- 7.4 The Department has published information for primary care trusts on its website to support the 2005 Regulations. It is at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4107573. The Department is currently completing a major overhaul of this guidance and a revised version, which will incorporate these amendments as appropriate, is expected to be published by the summer of 2008.

Consolidation

7.5 As these amendments involve only minor amendments, the Department does not propose to consolidate the 2005 Regulations.

8. Impact

8.1 The Department considers these amendments are technical in effect. Whilst the introduction of common requirements for practice leaflets may give rise to some costs for some businesses, these are considered minimal and will ensure consistency of information for the public across all providers. An Impact Assessment (IA) has therefore not been prepared.

8.2 No issues affecting equality have been identified for these amendments.

9. Contact

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