EXPLANATORY MEMORANDUM TO THE NHS (PHARMACEUTICAL SERVICES) (REMUNERATION FOR PERSONS PROVIDING PHARMACEUTICAL SERVICES (AMENDMENT) REGULATIONS 2007

2007 No. 674

1. This explanatory memorandum has been prepared by 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 This Instrument amends the NHS (Pharmaceutical Services) Regulations 2005 - SI 2005/641 ("the 2005 Regulations") and consequential amendments to related instruments.

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

3.1 These are the first regulations to be made under section 164 of the National Health Service Act 2006. Paragraphs 7.2 to 7.4 to this Memorandum set out the policy background to, and history of, sections 164 and 165.

4. Legislative Background

4.1 This instrument substitutes Regulation 56 of the 2005 Regulations. Regulation 56 makes provision for how remuneration for contractors who provide NHS pharmaceutical services is to be determined by the relevant authorities. Those authorities are the Secretary of State and NHS Primary Care Trusts.

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 policy background to the 2005 Regulations was set out in the Explanatory Memorandum accompanying those regulations. In brief, the 2005 Regulations:

- introduced from 1 April 2005 a new contractual framework for NHS community pharmacy services;

- implemented 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

- introduced requirements under the Health and Social Care Act 2001, which amended the National Health Services Act 1977, for pharmacists, companies, their directors and superintendent pharmacists to make declarations as to their suitability to provide pharmaceutical services (termed "fitness to practise").

7.2 This Instrument is essentially a technical amendment to the 2005 Regulations and substitutes Regulation 56 so that determinations of remuneration comply with the requirements of Section 164 of the NHS Act 2006. Section 164 is the statutory basis for remunerating NHS pharmaceutical contractors. Remuneration can cover salary, fees, allowances, and partial or full reimbursement of expenses. For pharmaceutical contractors, such expenses principally comprise being paid for the NHS drugs and appliances that they supply against authorised NHS prescriptions. Remuneration details are published monthly in the Drug Tariff which extends to nearly 600 pages and is distributed to the NHS and to contractors in England and Wales. The Tariff is the legal mechanism for paying pharmaceutical contractors. Regulation 56 makes provision for how remuneration is to be determined by the relevant authorities. Those authorities are the Secretary of State or other persons duly appointed by the Secretary of State (i.e. NHS Primary Care Trusts).

7.3 This change follows consolidation of the primary legislation set out in Sections 164 and 165 of the NHS Act 2006. Sections 164 and 165 respectively consolidate sections 43A and 44B of the NHS Act 1977. Those sections were originally inserted by section 7 of the Health and Social Security Act 1984 though never brought into force (except for section 7(4) which was brought into force on Royal Assent). The rest of section 7 (i.e. sections 7 (1) to (3)), was subsequently substituted by section 10 of the Health Act 1999 and then amended by the National Health Service Reform and Health Care Professions Act 2002. None of these later amendments were brought into force. Section 7(4) in effect enabled the Department to treat the amended provisions as if they were in force although they were not. The Department relied on this in order to make and to amend the Drug Tariff as a consequence of the original section 7(4) of the 1984 Act. The National Health Service (Pre-Consolidation Amendments) Order 2006 amended and updated sections 43A and 43B of the NHS Act 1977 and provided for the repeal of section 7(4) of the Health and Social Security Act 1984. The Order came into force immediately before 1 March 2007. The new Sections 164 and 165 in the Consolidation Act came into force on 1 March 2007.

7.4 Section 164 sets out the powers for determining remuneration for persons providing pharmaceutical services. It requires remuneration to be determined by the relevant determining authority. It is mainly a regulating making

provision and sets out various criteria which can be used in making that determination. Section 164(9) specifically provides that determinations of remuneration can relate to periods covering a future or an earlier date. Where such determinations relate to an earlier date they must not, taking the determination as a whole, be detrimental to the persons providing services.

7.5 The determinations which are made are complex and vary according to the nature of the particular determination. So, for example, a determination relating to a specific fee may be made by reference to the amount of funding available, the expected number of fees which that funding has to cover, and the levels of related fees. Where a determination relates to the particular price at which a contractor will be reimbursed for supplying a product, factors that may be taken into account in determining that price might include the suppliers' lists of published prices, their statements of sales volumes and the prices they achieved and a calculation of the discount that may be obtained from suppliers relative to their overall value. It is necessary therefore for the Regulations to be as flexible as possible and not to limit the factors that the Secretary of State may take into account when making a particular determination.

7.6 Prior to making a determination, Section 165 requires the Secretary of State to consult bodies which represent pharmaceutical contractors and can consult other bodies if appropriate. Section 165 sets out the scope of the determinations of remuneration that can be made. This scope is deliberately drawn widely so that it can, for example, correct errors in previous determinations or set certain conditions that must be satisfied before a contractor is paid.

7.7 Where a determination concerns the price of a drug or appliance, this Instrument requires the Secretary of State to consult representative bodies on the process for determining the proposed price, rather than on the proposed price itself, unless consultation cannot effectively be carried out in any other way.

Consultation

7.8 The Department has consulted representative bodies for community pharmacy, primary medical services, dispensing doctors and appliance contractors on the proposed instrument. The Department received comments from representatives of community pharmacy and primary medical services suggesting modifications to the phrasing and wording used. The Department has explained that, in this instance, the original phrasing and wording is to be preferred as this does not require the introduction of new terms and consequential further definitions. Representatives of community pharmacy also sought clarification concerning the actual date of publication as it has to be produced several days in advance of the month in which the changes take effect. The Department has explained that the Drug Tariff will specify the date on which it is due to take effect, the date any particular provisions are to take effect if these differ, and the date it is published. The Department will

continue to discuss with interested parties any technical operational issues that may arise.

Guidance

7.9 The Department has published general information for Primary Care Trusts to support the introduction of the 2005 Regulations at:

http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4107573&chk=5TqNtc

and more specific guidance relating to the contractual framework for community pharmacies at

http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4109256&chk=/hpb.

The Department will update that latter information to reflect the amendments set out here.

Consolidation

7.10. As this Instrument concerns technical amendments to the current regulations to implement the provisions of the NHS Act 2006, the Department does not propose to consolidate the 2005 Regulations.

8. Impact

8.1 A Regulatory Impact Assessment (RIA) has not been prepared as these Regulations are a technical amendment to the 2005 Regulations and impose no new burden on pharmaceutical contractors.

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