STATUTORY INSTRUMENTS

2007 No. 1320

NATIONAL HEALTH SERVICE, ENGLAND AND WALES
NATIONAL HEALTH SERVICE, SCOTLAND
HEALTH AND PERSONAL SOCIAL SERVICES, NORTHERN IRELAND

The Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007

Made - - - -	*19th April 2007*
Laid before Parliament	*1st May 2007*
Coming into force - -	*25th May 2007*

The Secretary of State for Health in exercise of the powers conferred by sections 261(7), 262(1), 264, 265, 266(2) and 272(7) and (8) of the National Health Service Act 2006(**1**) makes these Regulations.

The Secretary of State for Health has consulted in accordance with sections 261(7), 262(1), 264(1) and 265(9) of the National Health Service Act 2006.

Citation and commencement

1. These Regulations may be cited as the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007 and shall come into force on 25th May 2007.

Interpretation

2.—(1) In these Regulations—

"the 1978 Act" means the National Health Service (Scotland) Act 1978(**2**);

"the 2006 Act" means the National Health Service Act 2006;

"the 2006 Wales Act" means the National Health Service (Wales) Act 2006(**3**);

(**1**) 2006 c. 41. Sections 33 to 38 of the Health Act 1999 (c. 8) were re-enacted as sections 261 to 266 of the National Health Service Act 2006.
(**2**) 1978 c. 29.
(**3**) 2006 c. 42.

"the 1972 Order" means the Health and Personal Social Services (Northern Ireland) Order 1972(**4**);

"Annual Financial Return" means the Annual Financial Return that must be submitted by a scheme member under the PPRS;

"branded health service medicine" means a health service medicine which—

(a) is identifiable by and traded under a specific name given to it by the manufacturer, supplier or holder of a marketing authorisation relating to it;

(b) is a medicinal product in respect of which a marketing authorisation has been granted; and

(c) is not—

(i) in relation to England, listed in Schedule 1 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004(**5**);

(ii) in relation to Scotland, specified in any directions given by the Scottish Ministers under section 17N(6) (other mandatory contract terms)(**6**) of the 1978 Act as being drugs, medicines or other substances which may not be ordered by a GMS contractor for patients in the provision of primary medical services under a general medical services contract made under section 17J (health boards power to enter into general medical services contracts)(**7**) of the 1978 Act in relation to Scotland; or

(iii) in relation to Northern Ireland, listed in Schedule 1 to the Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc.) Regulations (Northern Ireland) 2004(**8**);

"dispensing doctor" means a registered medical practitioner who provides pharmaceutical services;

"GMS contractor" means a person providing primary medical services under a general medical services contract made under—

(a) section 84 (general medical services contracts: introductory) of the 2006 Act in relation to England;

(b) section 42 (general medical services contracts: introductory) of the 2006 Wales Act in relation to Wales;

(c) section 17J (health boards power to enter into general medical services contracts) of the 1978 Act in relation to Scotland; or

(d) article 57 of the 1972 Order in relation to Northern Ireland;

"health service hospital" means a hospital owned or managed by a health service body;

"health service body" means—

(a) a Strategic Health Authority, Special Health Authority, Primary Care Trust, National Health Service Trust or NHS foundation trust established or continued under the 2006 Act;

(b) a Local Health Board established or continued under the 2006 Wales Act;

(c) a Health Board or Special Health Board constituted under section 2 (Health Boards and Special Health Boards)(**9**) of the 1978 Act;

(**4**) S.I. 1972/1265 (N.I. 14).
(**5**) S.I. 2004/629.
(**6**) Section 17N was inserted by section 4 of the Primary Medical Services (Scotland) Act 2004 (asp 1).
(**7**) Section 17J was inserted by section 4 of the Primary Medical Services (Scotland) Act 2004 (asp 1).
(**8**) S.R. 2004/142.
(**9**) Section 2 was amended by section 28 of and Schedules 9 and 10 to the National Health Service and Community Care Act 1990 (c.19) ("the 1990 Act"), paragraph 1 of Schedule 1 to the National Health Service Reform (Scotland) Act 2004 (asp

(d) a Health and Social Services Board established under the 1972 Order;

(e) a special health and social services agency established under the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990(**10**);

(f) the Common Services Agency for the Scottish Health Service constituted under section 10 (Common Services Agency)(**11**) of the 1978 Act;

(g) the Northern Ireland Central Services Agency for the Health and Social Services established under the 1972 Order; or

(h) a Health and Social Services trust established under the Health and Personal Social Services (Northern Ireland) Order 1991(**12**);

"marketing authorisation" means a marketing authorisation for a medicinal product for human use granted—

(a) by the competent authority of the United Kingdom in accordance with Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use(**13**); or

(b) by the European Commission in accordance with Regulation (EC) No. 726/2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency(**14**);

"pharmaceutical services" means pharmaceutical services within the meaning of—

(a) section 126 (arrangements for pharmaceutical services) of the 2006 Act in England;

(b) section 80 (arrangements for pharmaceutical services) of the 2006 Wales Act in Wales;

(c) section 27 (arrangements for provision of pharmaceutical services)(**15**) of the 1978 Act in Scotland; or

(d) article 63 (arrangements for pharmaceutical services) of the 1972 Order in Northern Ireland;

"PMS contractor" means a person providing primary medical services under—

(a) a personal medical services agreement made under section 92 (arrangements by Strategic Health Authorities for the provision of primary medical services) in relation to England;

(b) an agreement made under section 50 (arrangements by Local Health Boards for the provision of primary medical services) of the 2006 Wales Act in relation to Wales;

(c) an agreement made under section 17C (personal medical or dental services)(**16**) of the 1978 Act in relation to Scotland; or

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7) ("the 2004 Act") and paragraph 2 of Schedule 2 to the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13) ("the 2005 Act").

(**10**) S.I. 1990/247 (N.I. 3).

(**11**) Section 10 was amended by Schedule 10 to the 1990 Act, section 65 of and paragraph 44 of Schedule 4 to the Health Act 1999 (c.8), Schedule 2 to the 2004 Act and paragraph 2 of Schedule 2 to the 2005 Act.

(**12**) S.I. 1991/194 (N.I. 1).

(**13**) OJ No. L311, 28.11.2001; Directive 2001/83/EC was amended by Directive 2002/98/EC of the European Parliament and of the Council (OJ No. L33, 8.2.2003, p.30), by Commission Directive 2003/63/EC (OJ No. L159, 27.6.2003, p.46), by Directive 2004/24/EC of the European Parliament and of the Council (OJ No. L136, 30.4.2004, p.85) and by Directive 2004/27/EC of the European Parliament and of the Council (OJ No. L136, 30.4.2004, p.34).

(**14**) OJ No. L136, 30.4.2004, p.1.

(**15**) Section 27 was amended by section 20(2) of the Health Services Act 1980 (c. 53), section 3(3) of the National Health Service (Amendment) Act 1986 (c. 66), S.I. 1987/2202, paragraph 19(7) of Schedule 9 to the 1990 Act, section 3 of the Medicinal Products: Prescription by Nurses etc. Act 1992 (c. 28) and paragraph 44 of Schedule 2 to the National Health Service (Primary Care) Act 1997 (c.46) ("the 1997 Act").

(**16**) Section 17C was inserted by sections 21(2) and 41(3) of the 1997 Act and amended by section 2(2)(a), (b), (c), (d) and (e) of the Primary Medical Services (Scotland) Act 2004 (asp 1) and paragraph 12 of Schedule 3 to the National Health Service Reform and Health Care Professions Act 2002 (c. 17). Section 17C retains its original heading of "personal medical or dental services" although the section now relates to primary medical services and personal dental services.

(d) a personal medical services agreement made under article 15B (provision of primary medical services or personal dental services) of the 1972 Order in relation to Northern Ireland;

"PPRS" means the Pharmaceutical Price Regulation Scheme(**17**);

"quarter" means the period—

(a) 1st January to 31st March;

(b) 1st April to 30th June;

(c) 1st July to 30th September; or

(d) 1st October to 31st December;

"relevant scheme member" means a scheme member who falls within regulation 3(1) but who does not fall within regulation 3(2) (unless regulation 3(3) applies);

"retail pharmacist" means a person lawfully conducting a retail pharmacy business in accordance with section 69 (general provisions) of the Medicines Act 1968(**18**) who provides pharmaceutical services;

"sales income" means income from sales after deduction of all trade and other discounts (howsoever named) including settlement discounts, rebates and sales taxes;

"supply" means supply by way of sale; and

"wholesaler" means a person who—

(a) is a holder of a wholesale dealer's licence within the meaning of subsection (3) and (3A) of section 8 (provisions as to manufacture and wholesale dealing)(**19**) of the Medicines Act 1968; and

(b) is not a retail pharmacist, dispensing doctor, GMS contractor or PMS contractor nor is a health service hospital.

(2) A health service medicine is supplied on the date on which a contract for its sale for health service use is concluded.

Information

3.—(1) Except as provided in paragraph (2), this regulation applies to any manufacturer or supplier of branded health service medicines to whom the PPRS applies ("scheme member") who—

(a) holds either a wholesale dealer's licence within the meaning of subsection (3) and (3A) of section 8 (provisions as to manufacture and wholesale dealing) of the Medicines Act 1968 or a marketing authorisation in respect of those branded health services medicines; and

(b) during the 12 months ending on 31st December of the year preceding that in which any quarter falls, supplied branded medicines for health service use to the value of £25 million or more.

(2) Except as provided in paragraphs (3) and (4), the obligation to provide information under this regulation shall not apply to a scheme member who has agreed as part of its obligations under the PPRS to provide within the time limits set out in paragraph (6) such information relating to the sales income in respect of each branded health service medicine as is agreed between the Secretary of State and the industry body.

(**17**) Current version first published: November 2004. The Pharmaceutical Price Regulation Scheme is available on the Department of Health's website at: http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4093228&chk=qW14At.

(**18**) 1968 c. 67. Section 69 was amended by section 1 of and paragraph 5 of the Schedule to the Pharmacists (Fitness to Practise) Act 1997 (c. 19), the Statute Law Repeals Act 1993 (c. 50) and Article 26(b) of and paragraph 4 of Schedule 5 to S.I. 1976/1213.

(**19**) Section 8(3) was substituted by S.I. 1977/1050 and amended by S.I. 1992/604, 1993/834, 2004/1031 and 2006/2407. Section 8(3A) was inserted by S.I. 1993/384 and amended by S.I. 2002/236 and 2004/1031.

(3) If the Secretary of State and the industry body fail to reach an agreement as referred to in paragraph (2), paragraphs (4) to (6) shall apply to a scheme member who falls within paragraph (1).

(4) This regulation shall continue to apply to a relevant scheme member who has received a demand for a penalty under regulation 4 until that penalty has been fully paid.

(5) A relevant scheme member shall, to the extent that the information is available to it (or would be available if it took reasonable steps to make it available), provide to the Secretary of State in respect of each branded health service medicine the following information in accordance with paragraph (6) in respect of each quarter (being a quarter falling in whole or in part after the coming into force of these Regulations) in which it has supplied branded health service medicines—

(a) the sales income in respect of each pack size and strength of a branded product sold by it to wholesalers, including the total number of products sold;

(b) the sales income in respect of each pack size and strength of a branded product supplied by it to retail pharmacists, including the total number of products sold;

(c) the sales income in respect of each pack size and strength of a branded product supplied by it to—

(i) dispensing doctors or where that doctor is part of a partnership or is employed by a person or body to provide primary medical services to that partnership, person or body;

(ii) GMS contractors; or

(iii) PMS contractors,

including the total number of products sold;

(d) the sales income in respect of each pack size and strength of a branded product supplied by it to health service hospitals, including the total number of products sold; and

(e) information about discounts given by it to wholesalers, retail pharmacists, dispensing doctors, GMS contractors, PMS contractors or health service hospitals which cannot be specifically attributed to a specific branded product or pack size or strength of a specific branded product.

(6) Information supplied pursuant to paragraph (5) in respect of a quarter shall be given no later than the time specified in the right hand column of the table below in relation to the quarter specified in the left hand column:

Quarter in which supply was made	*Information to be received by the Secretary of State not later than*
Ending on 31st March	30th April in the same year as the quarter falls
Ending on 30th June	31st July in the same year as the quarter falls
Ending on 30th September	31st October in the same year as the quarter falls
Ending on 31st December	31st January in the year next following the year in which the quarter falls

Penalties

4.—(1) A relevant scheme member who contravenes regulation 3(5) or (6) or both provisions shall, on the demand of the Secretary of State, pay to her a daily penalty calculated under the Schedule to these Regulations.

(2) A demand made under paragraph (1) shall be made by a notice—

(a) in writing, or

(b) transmitted by electronic means in a legible form which is capable of being used for subsequent reference,

addressed to the scheme member in question and it shall state the amount of the penalty calculated up to the date of the demand and the period within which it shall be paid.

Appeals

5. A relevant scheme member on whom a notice has been served under regulation 4 shall have a right of appeal in accordance with regulations made under section 265(5) of the 2006 Act.

Transitional provision

6. In respect of the quarter commencing on 1st April 2007 the requirement to provide information under regulation 3 applies in respect of the period 1st May 2007 to 30th June 2007.

Revocation

7. The following regulations are revoked from the date of coming into force of these Regulations—

(a) the Health Service Medicines (Control of Prices of Branded Medicines) Regulations 2000(**20**);

(b) the Health Service Medicines (Control of Prices of Specified Generic Medicines) Regulations 2000(**21**); and

(c) the Health Service Medicines (Information on the Prices of Specified Generic Medicines) Regulations 2001(**22**).

Signed by authority of the Secretary of State

Hunt
Minister of State
Department of Health

19th April 2007

(**20**) S.I. 2000/123.
(**21**) S.I. 2000/1763.
(**22**) S.I. 2001/3798.

THE SCHEDULE

Regulation 4

PENALTIES

1. The daily penalty payable by a relevant scheme member who contravenes regulation 3(5) or (6) or both provisions shall be calculated by reference to—

(a) the entry in column (1) of the following table within which the total value of his sales for the health service falls;

(b) the amount specified in column (2) opposite that entry in respect of each day of the contravention; and

(c) the amount specified in column (3) opposite that entry in respect of each subsequent day of that contravention.

THE TABLE

Health service sales of relevant scheme member	*Daily penalty for first 14 days*	*Daily penalty for subsequent days*
Column (1)	*Column (2)*	*Column (3)*
Less than £100 million	£2,500	£5,000
£100 million or more	£5,000	£10,000

2. For the purposes of this Schedule, the health service sales of the relevant scheme member shall be calculated at the time the penalty becomes payable by reference to the amount recorded by that scheme member in the Annual Financial Return most recently submitted by it.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which apply to the United Kingdom, require the provision of information in relation to the prices of branded medicines which are supplied for the purposes of the health services in England, Wales, Scotland and Northern Ireland (see the definition of "health service" in section 266(6) of the National Health Service Act 2006).

These Regulations apply only to medicines in respect of which marketing authorisations have been granted that are supplied by companies which are members of the Pharmaceutical Price Regulation Scheme (PPRS). The 2005 PPRS is the present voluntary price regulation scheme. It was agreed in November 2004 between the Department of Health and the Association of the British Pharmaceutical Industry and came into effect on 1st January 2005. The PPRS is available on the Department of Health's website at http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4093228&chk=qW14At.

Regulation 3 requires information on the sales of branded health service medicines to be supplied to the Secretary of State.

Provision is made for the recovery of penalties where there is a failure to provide information under regulation 3 and for appeals (regulations 4 and 5).

Transitional provision is made for the period before the coming into force of these Regulations which would otherwise fall within the scope of these Regulations (regulation 6).

Regulation 7 revokes various Regulations which no longer reflect the current policy on statutory price controls of medicines supplied for NHS purposes.

A Regulatory Impact Assessment has been prepared and copies may be obtained from the Department of Health, Zone 456D, Skipton House, 80 London Road, London, SE1 6LH.