

2013 No. XXX

**NATIONAL HEALTH SERVICE, ENGLAND AND
WALES**

NATIONAL HEALTH SERVICE, SCOTLAND

**HEALTH AND PERSONAL SOCIAL SERVICES,
NORTHERN IRELAND**

**The Health Service Medicines (Control of Prices and Branded
Medicines) Regulations 2013**

<i>Made</i>	- - - -	2013
<i>Laid before Parliament</i>		2013
<i>Coming into force</i>	- -	2013

The Secretary of State for Health, in exercise of the powers conferred by sections 261(7), 262(1), 263, to 265, 266(1) and (2) and 272(7) and (8) of the National Health Service Act 2006(a), makes these Regulations.

The Secretary of State for Health has consulted in accordance with sections 261(7), 262(1), 263(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 (Control of Prices and Branded Medicines) Regulations 2013 and shall come into force on XXX.

Interpretation

2.—(1) In these Regulations—

“the 1972 Order” means the Health and Personal Social Services (Northern Ireland) Order 1972(b);

“the 1978 Act” means the National Health Service (Scotland) Act 1978(c);

“the 2006 Act” means the National Health Service Act 2006;

“the 2006 Wales Act” means the National Health Service (Wales) Act 2006(a);

(a) 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.

(b) S.I. 1972/1265 (N.I.14).

(c) 1978 (c.29).

“the Board” means the National Health Service Commissioning Board established by section 1H of the 2006 Act^(b)(the National Health Service Commissioning Board and its general functions);

“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;
 - (i) in relation to Scotland, specified in any directions given by the Scottish Minister under section 17N(6) (other mandatory contract terms)^(c) 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)^(d) of the 1978 Act in relation to Scotland; or
 - (ii) 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;

“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—

- (d) section 84 (general medical services contracts: introductory)^(e) of the 2006 Act in relation to England;
- (e) section 42 (general medical services contracts: introductory) of the 2006 Wales Act in relation to Wales;
- (f) section 17J (health boards power to enter into general medical services contracts) of the 1978 Act in relation to Scotland; or
- (g) 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—

- (h) a Special Health Authority, National Health Service Trust or NHS foundation trust established or continued under the 2006 Act;
- (i) a Local Health Board established or continued under the 2006 Wales Act;
- (j) a Health Board or Special Health Board constituted under section 2 (Health Boards and Special Health Boards)^(f) of the 1978 Act;
- (k) a Health and Social Services Board established under the 1972 Order;
- (l) a Special Health and Social Services Agency established under the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990;

(a) 2006 (c.42).

(b) Section 1H was inserted by the Health and Social Care Act 2012 (c.7), section 9(1).

(c) Section 17N was inserted by the Primary Medical Services (Scotland) Act 2004 (asp1), section 4.

(d) Section 17J was inserted by the Primary Medical Services (Scotland) Act 2004 (asp1), section 4.

(e) Section 84 was amended by the Health and Social Care Act 2012 (c.7), Schedule 4(4) paragraph 31(2), 31(3), 31(4) subject to savings and transitional provisions specified by 2013/160 arts 5-9.

(f) Section 2 was amended by the National Health Service and Community Care Act 1990 (c.19) (“the 1990 Act”), section 28 and Schedules 9 and 10, the National Health Service Reform (Scotland) Act (asp7) (the 2004 Act”), Schedule 1 paragraph 1 and the Smoking, Health and Social Care (Scotland) Act 2005 (asp13) (“the 2005 Act”), Schedule 2 paragraph 2.

- (m) the Common Services Agency for the Scottish Health Service constituted under section 10 (Common Services Agency)(a) of the 1978 Act;
- (n) the Northern Ireland Central Services Agency for the Health and Social Services established under the 1972 Order; or
- (o) a Health and Social Services trust established under the Health and Personal Social Services (Northern Ireland) Order 1991;

“marketing authorisation” means a marketing authorisation for a medicinal product for human use granted—

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

“pharmaceutical services” means pharmaceutical services within the meaning of—

- (r) section 126 (arrangements for pharmaceutical services)(c) of the 2006 Act in England;
- (s) section 80 (arrangements for pharmaceutical services)(d) of the 2006 Wales Act in Wales;
- (t) section 27 (arrangements for provision of pharmaceutical services)(e) of the 1978 Act in Scotland; or
- (u) article 63 (arrangements for pharmaceutical services) of the 1972 Order in Northern Ireland;

“PMS contractor” means a person providing primary medical services under—

- (v) a personal medical services agreement made under section 92 (arrangements by the Board)(f) for the provision of primary medical services) of the 2006 Act in relation to England;
- (w) 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;
- (x) an agreement made under section 17C (personal medical or dental services)(g) of the 1978 Act in relation to Scotland; or
- (y) 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;

(a) Section 10 was amended by the 1990 Act, Schedule 10, the Health Act 1999 (c.8), section 65 and Schedule 4 paragraph 44, the 2003 Act Schedule 2, the 2005 Act Schedule 2 paragraph 2 and the Patients Rights (Scotland) Act 2011 (asp5), section 17(1).

(b) OJ No. L311,28.11.2001; Directive 2001/82/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, p46), 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).

(c) Section 126 was amended by the Health and Social Care Act 2012 (c.7), section 63 and Schedule 4(7) paragraph 213.

(d) Section 80 was amended by the Health and Social Care Act 2012 (c.7), section 13(7)(l) and 220(8).

(e) Section 27 was amended by the Health Services Act 1990 (c.53), section 20(2), the National Health Service (Amendment) Act 1986 (c.66), section 3(3); S.I. 1987/2202; the 1990 Act, Schedule 9 paragraph 19(7), the Medicinal Products: Prescription by Nurses etc. Act 1992 (c.28), section 3, the National Health Service (Primary Care) Act 1997 (c.46) (“the 1997 Act”), Schedule 2 paragraph 44 and the Health and Social Care Act 2012 (c.7), section 220(2) and 213(7)(c).

(f) Words substituted by the National Treaty Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013/235 Schedule 2(1) paragraph 112(b).

(g) Section 17C was inserted by the 1997 Act, section 21(2) and 41(3) and amended by the Primary Medical Services (Scotland) Act 2004 (asp1), section 2(2)(a),(b),(c),(d) and (e), the National Health Service Reform and Health Care Professions Act 2002 (c.17), Schedule 3 paragraph 12 and the Health and Social Care Act 2012 (c.7), Schedule 21 paragraph 3(2)(a), subject to savings and transitional provisions specified in SI 2013/160 arts 5-9. 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.

“prescription only medicine” has the same meaning as in the Human Medicines Regulations 2012(a);

“presentation” means a particular form of a relevant medicine which may be distinguished from other forms of the medicine by reference to its active ingredients, strength and excipients, pack size, type of packaging, clinical indications or indicated method of administration for use in clinical practice;

“reference period” has the meaning in regulation 3(5);

“relevant medicine” means a medicine which is both a prescription only medicine and a branded health service medicine;

“retail pharmacist” means a person lawfully conducting a retail pharmacy business in accordance with section 69 (general provisions)(b) of the Medicines Act 1968 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—

(z) is a holder of a wholesale dealer’s licence within the meaning of regulation 18 (wholesale dealing in medicinal products)(c) of the Human Medicines Regulations 2012;

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

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

Control of prices

3.—(1) Subject to regulation 6 and paragraph (3) of this regulation, the maximum price which may be charged for the supply of a presentation to a health service hospital is the amount determined by reducing by $x\%$ the amount calculated by the following formula—

$$\frac{S}{V}$$

Where—

S is the net income from all sales of the presentation to health service hospitals during the reference period; and

V is the volume of sales of that presentation to health service hospitals during the reference period;

(2) Subject to regulation 6 and paragraph (3) of this regulation, the maximum price which may be charged for the supply of a presentation of a health service medicine which is not supplied to a health service hospital is the price at which that presentation was on sale on 1st December 2013 less x per cent, but without regard to any discount or other variation of the price which did not have general application on that date.

(3) This regulation does not apply—

(a) to a manufacturer or supplier who has, during the most recent complete calendar year, supplied branded health service medicines for health service use in the United Kingdom of a value less than £5 million.

(a) S.I. 2012/1916.

(b) Section 69 was amended by the Statute Law Repeals Act 1993 (c.50), Schedule (1) (XII) paragraph 1, the European Qualifications (Health and Social Care Professionals) Regulations 2007/3101 Pt 6, regulation 98(a), the Pharmacists and Pharmacy Technicians Order 2007/289, Schedule 1(1) paragraph 2(4)(b) and (c), the Pharmacy Order 2010/231 Schedule 4(1) paragraph 1(2)(a) and (b).

(c) Section 8 of the Medicines Act 1968 was re-enacted as regulation 18 of Human Medicines Regulation 2012.

- (b) To a manufacturer or supplier to whom a voluntary scheme for the supply of branded health service medicines applies at the time of a supply; or
- (c) Where the maximum price of a presentation is determined by the following regulations.
- (4) Where the amount determined under paragraph (1) or (2) results in an amount which includes a fraction of a penny, the maximum price is rounded down to the nearest whole penny.
- (5) The reference period is the most recent of the following periods to expire—
 - (a) in respect of 2014, the period beginning on 1st October 2013 and ending on 30th November 2013, and
 - (b) in respect of each subsequent year, the period beginning on 1st October 2013 and ending on 30th September 2014.

New products

4.—(1) Subject to paragraph (4), where a presentation was not on sale in the United Kingdom for health service purposes on 1st December 2013, the Secretary of State may specify the maximum price at which that presentation may be supplied for the purposes of the health service by a direction to a specific manufacturer or supplier.

(2) The maximum price for a presentation containing new active ingredients to which this regulation applies shall be determined by the Secretary of State having regard, among other things, to the following criteria—

- (a) the expected supplies of the presentation for health service purposes;
- (b) the cost of therapeutically equivalent medicines;
- (c) the cost of the presentation containing new active ingredients in other markets if it is available elsewhere in the world;
- (d) the cost of manufacture of the presentation;
- (e) the cost of research into and development of, the presentation;
- (f) whether the presentation consists of or contains a new active substance; and
- (g) the likelihood of the presentation being supplied at a particular price.

(3) The Secretary of State will determine the maximum price of a line extension presentation of a branded health service medicine by having regard to the quantity of the active ingredient or active ingredients in the presentation, the recommended dose, its therapeutic indications and route of administration and by considering any price proposed by the manufacturer or supplier of the presentation with the price of other presentations that are on the market in the United Kingdom.

(4) For the purposes of paragraph 3, a “line extension” means a branded health service medicine on sale in the United Kingdom which—

- (a) has the same product branding, and contains the same active ingredient or active ingredients as another presentation of a branded health service medicine which was on sale in the United Kingdom during the reference period; and
- (b) is a presentation in respect of which a maximum price has not previously been determined under these Regulations.

(5) This regulation does not apply to a manufacturer or supplier—

- (a) during any year in which it supplies branded health service medicines for health service use in the United Kingdom of a value less than £5 million; or
- (b) to whom a voluntary scheme for the supply of branded health service medicines applies at the time of a supply.

(6) When making determinations under this regulation, regard must be had to the audited accounts or other information supplied to the Secretary of State under regulation 9.

Low cost presentations

5.—(1) The maximum price which may be charged for a low cost presentation is the price at which that presentation was on sale for health service purposes in the United Kingdom during the most recent complete calendar year.

(2) In this paragraph—

“low cost presentation” means a presentation which has a reimbursement price of less than £2.00; and—

“reimbursement price” means the price which the presentation is reimbursed by the health service in the United Kingdom;

Exemptions

6. The Secretary of State may (whether or not he receives an application for an exemption from a manufacturer or supplier of a presentation) exempt, for such period as he may determine, a presentation from the effect of regulation 3,4,5 where he considers that an exemption is necessary to ensure adequate supplies of that presentation for health service purposes.

Increases

7.—(1) The Secretary of State may either—

- (a) on his own motion; or
- (b) on application made under paragraph (2),

increase the maximum price of a presentation by direction to a specific manufacturer or supplier.

(2) An application by a specific manufacturer or supplier to the Secretary of State for an increase of the maximum price of a presentation shall be made in writing and shall—

- (a) specify the presentation in respect of which the application is made,
- (b) state the reasons for the application, and
- (c) be accompanied by the information specified in paragraph (6).

(3) The Secretary of State shall, subject to paragraphs (4) and (5), within 90 days of receiving an application under this regulation either notify the applicant of his decision or notify the applicant that more information is required and, where further information is required, the Secretary of State shall notify the applicant of his decision within 90 days of receiving that further information.

(4) Where the number of applications received by the Secretary of State make it impracticable for him to reply to all or any of the applications within the 90 day period, he shall notify the applicant before the end of that period.

(5) In a case where the Secretary of State has given notice under paragraph (4), he shall make a decision not later than 60 days after the expiry of the 90 day period from receipt of the application, or if he has required further information under paragraph (3), not later than 150 days after the receipt of that further information.

(6) Where an application is made under this regulation, audited accounts for the latest accounting year for which they are available shall be supplied to the Secretary of State, and those accounts shall include the figures for that year in respect of branded health service medicines which show—

- (a) the supplies of those medicines for health service purposes;
- (b) any supply promotion costs in respect of those medicines;
- (c) any costs of research into, and development of, those medicines;
- (d) any non-recurring operational costs;
- (e) any other costs; and
- (f) total profit after interest charges and taxation.

(7) Where an application is made under this regulation, estimates of accounts for the two accounting years which follow the most recent one in respect of which accounts are required to be provided under paragraph (6) shall be supplied to the Secretary of State, showing the information of the kind required under that paragraph.

Enforcement

8.—(1) Any manufacturer or supplier who supplies a presentation for health service purposes at a price in excess of the maximum permitted by these Regulations shall be liable, on the demand of the Secretary of State, to pay to him a recoverable sum calculated under Schedule 1 to these Regulations.

(2) A demand made under paragraph (1) shall be made by a notice in writing addressed to the manufacturer or supplier in question and it shall state the amount of the recoverable sum calculated up to the date of the demand and the period within which it shall be paid.

(3) The recoverable sum, or any part of it, which has not been paid to the Secretary of State within the period specified in the demand shall carry interest at 2.5 per cent above the rate announced from time to time by the Monetary Policy Committee(a) of the Bank of England and for the time being in force as the official dealing rate, being the rate at which that Bank is willing to enter into transactions for providing short term liquidity in the money markets.

Information

9.—(1) Except as provided in paragraph (2), this regulation applies to any manufacturer or supplier of branded health service medicines who—

- (a) holds either a wholesale dealer's licence within the meaning of regulation 18 (wholesale dealing in medicinal products) of the Human Medicines Regulations 2012(b) or a marketing authorisation in respect of those branded health service medicines; and
- (b) has, during the most recent complete calendar year, supplied branded health service medicines for health service use in the United Kingdom with a relevant cost of £5 million or more.

(2) Except as provided in paragraph (4), the obligation to provide information under this regulation shall not apply to a manufacturer or supplier of branded health service medicines to whom a voluntary scheme applies who has agreed as part of its obligations under the scheme 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 required by the scheme.

(3) For any period during which there is no voluntary scheme, paragraphs (5) and (6) shall apply to a manufacturer or supplier who falls within paragraph (1).

(4) This regulation shall continue to apply to a manufacturer or supplier who has received a demand for a penalty under regulation 4 until that penalty has been fully paid.

(5) A manufacturer or supplier of branded health service medicines 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 the following information in accordance with paragraph (6) in respect of each branded health service medicine which it supplies for the purposes of the health service—

- (a) the sales income in respect of each presentation of branded product supplied by it to wholesalers, including the total number of products supplied;
- (b) the sales income in respect of each presentation of a branded product supplied by it to retail pharmacists, including the total number of products supplied;
- (c) the sales income in respect of each presentation of a branded product supplied by it to—

(a) The Monetary Policy Committee was constituted on a statutory basis by section 13 of the Bank of England Act 1998 (c.11), as amended by the Financial Services Act 2012 (c. 21) Pt 1 section 1(2).

(b) S.I. 2012/1916.

- (i) dispensing doctors or, where a dispensing doctor is part of a partnership or is employed by a person or body to provide primary medical services to a partnership, that person or body;
 - (ii) GMS contractors;
 - (iii) PMS contractors; or
 - (iv) Persons not mentioned in this paragraph, including the total number of products supplied;
 - (d) the sales income in respect of each presentation of a branded product supplied by it to health service hospitals, including the total number of products supplied; and
 - (e) information about discounts given by it, specifying separately discounts given to wholesalers, retail pharmacists, dispensing doctors, GMS contractors, PMS contractors, health service hospitals and others.
- (6) The information required by paragraph (5) shall be supplied for—
- (a) the period of 2 months starting on 1st October 2013 within 14 days of the end of that period, and
 - (b) 2014 and each subsequent year within 28 days of the end of that year.
- (7) Where a manufacturer or supplier is required to provide information to the Secretary of State under this paragraph—
- (a) if that manufacturer or supplier is in possession of an audited copy of that information, that audited copy is to be provided with information on the person who conducted the audit and the purposes, scope and date of the audit; and
 - (b) in any other case, the manufacturer or supplier shall provide information to demonstrate how the information supplied under this paragraph has been quality assured.

Penalties

10.—(1) A manufacturer or supplier of a branded health service medicine who contravenes regulation 9(5) or (6) or both provisions shall, on the demand of the Secretary of State, pay to him a daily penalty calculated under Schedule 2 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 manufacturer or supplier 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

11. A manufacturer or supplier of a branded health service medicine on whom a notice has been served under regulation 9 shall have a right of appeal in accordance with regulations made under section 265(5) of the 2006 Act.

Review

12.—(1) Before the end of review period, the Secretary of State must—

- (a) carry out a review of these Regulations;
- (b) set out the conclusions of the review in a report; and
- (c) publish the report.

(2) The report must in particular—

- (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;
- (b) assess the extent to which those objectives are achieved; and
- (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(3) The Secretary of State may exclude from the published report anything the publication of which the Secretary of State considers to be contrary to the interests of national security.

(4) “Review period” means the period of five years beginning with the day on which this regulation comes into force.

Revocation

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

- (a) The Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007;
- (b) the Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) 2008;
- (c) the Health Service Medicines (Control of Prices and Supply of Information) Amendment Regulations 2012;

Signed by authority of the Secretary of State for Health

Date

Minister of State
Department of Health

SCHEDULE 1

Regulation 8(1)

Recoverable Sums

1. For the purposes of regulation 8, the recoverable sum shall be the sum of—

- (a) the difference between the amount which a person would have received had the product been supplied at the maximum price and the amount that the person actually received; and
- (b) the amount calculated by multiplying that difference by the appropriate additional percentage specified in the Table in paragraph 2.

2. In respect of a contravention described in column (1) of the following table, the appropriate additional percentage is specified opposite in column (2).

THE TABLE

<i>Contravention</i>	<i>Additional Percentage</i>
<i>Column (1)</i>	<i>Column (2)</i>
First contravention	5 per cent
Second contravention	15 per cent
Third contravention	25 per cent
Fourth contravention	35 per cent
Fifth or subsequent contravention	50 per cent

3. For the purposes of this Schedule—

- (a) “second contravention” means a contravention which occurs where a presentation continued to be supplied in excess of the maximum price for a period of two months after the first contravention which relates to that presentation; and
- (b) each subsequent contravention occurs where the same presentation continues to be supplied for a further period of two months from the date of a previous contravention which relates to that product.

SCHEDULE 2

Regulation 10(1)

Penalties

1. The daily penalty payable by a manufacturer or supplier of a branded health service medicine who contravenes regulation 9(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

<i>Health service sales of manufacturer or supplier of a branded medicine</i>	<i>Daily penalty for first 14 days</i>	<i>Daily penalty for subsequent days</i>
<i>Column (1)</i>	<i>Column (2)</i>	<i>Column (3)</i>
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 manufacturer or supplier of a branded health service medicine shall be calculated at the time the penalty becomes payable by reference to its total sales in the United Kingdom as shown in its most recent audited accounts.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which apply to the United Kingdom, consolidate the Health Service Medicines (Information Relating to Sales of Branded Medicines etc) Regulations 2007, the Health Service Medicines (Control of Prices and Supply of Information) No.2 Regulations 2008 [,] [and] the Health Service Medicines (Control of Prices and Supply of Information) Amendment Regulations 2012 [and the Health Service Medicines (Control of Prices and Supply of Information) Amendment Regulations 2013].

These Regulations control the prices of presentations of branded medicines and 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 and that are supplied by companies which are members of the Pharmaceutical Price Regulations Scheme (PPRS) or to which the statutory scheme applies. The 2009 PPRS is the present voluntary price regulation scheme. It was agreed between the Department of Health and the Association of British Pharmaceutical Industry in 2008 and came into effect on 1st January 2009. The PPRS is available on the Department of Health’s website at.....

Regulation 2 includes the definition of a presentation.

Regulation 3 specifies the maximum price which may be charged for the supply of presentations by any manufacturer or supplier who is not a member of a voluntary scheme and except where regulation 4 or 5 apply. Separate maximum prices apply to supplies of medicines to health service hospitals and to supplies other than to health service hospitals. The maximum price that applies to health service hospitals is to be calculated by the net income from all sales of presentation to health service hospitals during the reference period (which is defined at paragraph (3)(6)), divided by the volume of sales of that presentation to health service hospitals during the reference period. The maximum price that applies to other supplies is the price at which that presentation was on sale on 1st December 2013 less x per cent, but without regard to any discount or other variation of the price which did not have general application on that date. These maximums do not apply to supplies of a value less than £5 million.

Regulation 5 defines a “low cost presentation” as a presentation with a reimbursement price of less than £2.00, and specifies that the maximum price which may be charged for a low cost presentation is the price at which that presentation was on sale for health service purposes in the United Kingdom, during the most recent complete calendar year.

Regulation 9 requires information on the sale of branded health service medicines to be supplied to the Secretary of State at yearly intervals, by any manufacturer or supplier of a branded health service medicine (both those in the voluntary scheme and those outside that scheme).

Provision is made for the recovery of penalties where there is a failure to provide information under regulation 9 and for appeals (regulations 10 and 11).

Regulation 13 requires the Secretary of State to review the operation and effect of these Regulations and publish a report within five years after the Regulations come into force. Following the review it will fall to the Secretary of State to consider whether the Regulations should be revoked or continue in force with or without amendments.

Regulation 14 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, London Road, London SE1 6LH.