STATUTORY INSTRUMENTS

2008 No. 1938

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

The Health Service Branded Medicines (Control of Prices and Supply of Information) Regulations 2008

Made - - - -	*19th July 2008*
Laid before Parliament	*21st July 2008*
Coming into force - -	*1st September 2008*

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

The Secretary of State 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, commencement and interpretation

1.—(1) These Regulations may be cited as the Health Service Branded Medicines (Control of Prices and Supply of Information) Regulations 2008 and shall come into force on 1st September 2008.

(2) In these Regulations—

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

"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; and

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

(**1**) 2006 c.41.

"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(**2**); or

(b) by the European Commission under Council Regulation (EEC) No.2309/93(**3**) or 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(**4**);

"prescription only medicine" has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997(**5**);

"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 and excipients, pack size, type of packaging, clinical indications or indicated method of administration for use in clinical practice;

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

"supply" means supply by way of sale.

Control of prices

2.—(1) The maximum price which may be charged by any manufacturer or supplier for the supply of a presentation is the reference price.

(2) In this regulation "reference price" in relation to a presentation means the reference price which was used for the purpose of pricing prescriptions for that presentation by the NHS Business Services Authority(**6**) on 29th February 2008 and is now published in respect of that presentation on the Department of Health website(**7**).

(3) This regulation does not apply to a manufacturer or supplier to whom a voluntary scheme applies at the time of a supply or where the maximum price of a presentation is determined by any of the following regulations.

New products

3.—(1) Where a presentation does not have a reference price as defined in regulation 2(2), 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 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;

(**2**) OJ No. L311, 28.11.2001, p.67; relevant amending instruments are Directive 2002/98/EC of the European Parliament and of the Council, OJ No. L33, 8.2.2003, p.30, Commission Directive 2003/63/EC, OJ No. L159, 27.6.2003, p.46, Directive 2004/24/EC of the European Parliament and of the Council, OJ No. L136, 30.4.2004, p.34 and Regulation (EC) No. 1901/2006 of the European Parliament and of the Council, OJ No. L378, 27.12.2006, p.1.
(**3**) OJ No. L214, 24.8.1993. p.1.
(**4**) OJ No. L136, 30.4.2004, p 1.
(**5**) S.I. 1997/1830; relevant amending instruments are 1998/108, 2002/549, 2003/696 and 2008/464.
(**6**) See S.I. 2006/632.
(**7**) www.dh.gov.uk, printed copies may be obtained from the Department of Health, Zone 456D, Skipton House, 80 London Road, London SE1 6LH.

(c) the cost of the presentation 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.

Exemptions

4. 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 2 or 3 where he considers that an exemption is necessary to ensure adequate supplies of that presentation for health service purposes.

Increases

5.—(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 from their receipt, 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

6.—(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 the Schedule 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) A 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(**8**) 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

7.—(1) The following regulation shall be substituted for regulation 3 of the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007(**9**).

"**Information**

3.—(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 subsections (3) and (3A) of section 8 (provisions as to manufacture and wholesale dealing) of the Medicines Act 1968(**10**) or a marketing authorisation in respect of those branded health services medicines; and

(b) during the 12 months ending on 31st December of the preceding year, supplied branded medicines for heath service use to the value of £25 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 ("scheme member") 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 supply 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 scheme member 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

(**8**) The Monetary Policy Committee was constituted on a statutory basis by section 13 of the Bank of England Act 1998 (c. 11).
(**9**) S.I. 2007/1320.
(**10**) 1968 c.67.

paragraph (6) in respect of each branded health service medicine which it supplies for the purposes of the health service—

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

(b) the supply 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 supplied;

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

(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 partnership, person or body;

(ii) GMS contractors; or

(iii) PMS contractors;

including the total number of products supplied;

(d) the supply 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 supplied; 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 required by paragraph (5) shall be supplied in accordance with the following table so that in respect of each month specified in the left hand column information will be supplied no later than the corresponding date in the right hand column.

Month in which supply was made	*Information to be received by the Secretary of State not later than*
September 2008	31 October 2008
October 2008	30 November 2008
November 2008	31 December 2008
December 2008	31 January 2009
January 2009	28 February 2009
February 2009	31 March 2009
March 2009	30 April 2009
April 2009	31 May 2009
May 2009	30 June 2009
June 2009	31 July 2009”

Appeals

8. Any manufacturer or supplier of a presentation in respect of whom the Secretary of State has made an enforcement decision under these Regulations shall have a right of appeal against that decision in accordance with regulations made under section 265(5) of the Act(**11**).

(**11**) See SI. 2000/124.

Duration of regulations

9. These Regulations shall cease to have effect on 1st September 2009.

Signed by the Secretary of State for Health

Alan Johnson
Secretary of State for Health

19th July 2008

SCHEDULE

Regulation 6(1)

RECOVERABLE SUMS

1. For the purposes of regulation 6, 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

Contravention	*Additional Percentage*
Column (1)	Column (2)
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 continues 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.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which apply to the United Kingdom, control the price of presentations of medicines which are supplied for health service purposes. They also require the supply of information relating to those presentations to the Secretary of State.

Regulation 1 includes a definition of presentation.

Regulation 2 specifies the maximum price which may be charged for a presentation which is supplied for health service purposes on or after 1st September 2008, except where regulation 3 applies. The maximum price is the "reference price" (as defined in paragraph (2)).

Regulation 3 makes provision for the specification of the maximum price for presentations which are first supplied for health service purposes on or after 1st March 2008 (new presentations).

Regulation 4 enables the Secretary of State to exempt presentations where a maximum price may jeopardise supplies of those presentations for the purposes of the health service.

Regulation 5 makes provision for increases in the price of presentations.

Regulation 6 and the Schedule make provision for enforcement of the controls on the prices of presentations of medicines by imposing specified penalties.

Regulation 7 amends the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007, so as to impose requirements on manufacturers and suppliers to provide information to the Secretary of State.

Regulation 8 makes provision for appeals from decisions made under these Regulations by the Secretary of State.

Regulation 9 provides for the Regulations to cease to have effect on 1st September 2009.

An Impact Assessment for these Regulations has been prepared and copies may be obtained from the Department of Health, Zone 456D, Skipton House, 80 London Road, London SE1 6LH