STATUTORY INSTRUMENTS

2000 No. 123

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

The Health Service Medicines (Control of Pricesof Branded Medicines) Regulations 2000

Made - - - -	*24th January 2000*
Laid before Parliament	*24th January 2000*
Coming into force - -	*14th February 2000*

The Secretary of State for Health, in exercise of powers conferred by sections 34(1), 36, 37(1) to (5) and (9) and 38(1) of the Health Act 1999(**1**), section 126(4) of the National Health Service Act 1977(**2**) and of all other powers enabling him in that behalf, having consulted the industry body, hereby makes the following Regulations:—

Citation and commencement

1. These Regulations may be cited as the Health Service Medicines (Control of Prices of Branded Medicines) Regulations 2000 and shall come into force on 14th February 2000.

Interpretation

2.—(1) In these Regulations—

"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**) Health Act 1999 c. 8.
(**2**) National Health Service Act 1977 c. 49, section 126(4) is applied in relation to powers conferred by the Health Act 1999 by section 62(4) of that Act.

"initial price" in relation to a presentation of a medicine means—

(a) the price of that presentation which was published on the internet at www.doh.gov.uk/pprsjuly.htm on 20th January 2000 by the Department of Health(**3**), or

(b) if no price has been so published but the price is so published of another presentation which is only distinguished by—

(i) type of packaging, that published price; or

(ii) pack size, the price calculated in direct proportion to that published price;

"maximum price" means the price under regulation 3 or, as the case may be, 4;

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

(a) by the competent authorities of the United Kingdom in accordance with Council Directive 65/65/EEC of 26th January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products(**4**); or

(b) by the European Agency for the Evaluation of Medicinal Products in accordance with Council Regulation (EEC) No. 2309/93 of 22nd July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products(**5**);

"presentation" means a particular form of a medicine which may be distinguished from other forms of that 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;

"supply" means supply by way of sale.

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

(3) Any reference in these Regulations to a numbered regulation is a reference to a regulation which bears that number in these Regulations and any reference to a numbered paragraph in a regulation is a reference to the paragraph in that regulation which bears that number, unless the context otherwise requires.

Control of prices

3. Subject to regulation 4, the maximum price which may be charged for the supply for health service purposes of a branded health service medicine of a particular presentation shall not exceed—

(a) 95.5 per cent of the initial price where, in aggregate, the supplies of branded health service medicines made by a manufacturer or supplier to the health service in the year ending 30th September 1999 exceeded £1,000,000, determined by reference to the amounts reimbursed by the Prescription Pricing Authority in respect of that year; and

(b) in any other case, the initial price of that presentation.

Increases

4.—(1) The Secretary of State may—

(a) on his own motion; or

(b) on application made in accordance with paragraph (2);

(**3**) Copies printed from the internet may be obtained from Room 130, Richmond House, 79 Whitehall, London SW1A 2NS.
(**4**) OJ No. L 22, 9.2.1965, p. 369 amended by Directives 66/454/EEC, 75/319/EEC, 83/570/EEC, 87/21/EEC, 89/341/EEC, 89/342/EEC, 89/343/EEC, 92/27/EEC, 92/73/EEC and 93/39/EEC.
(**5**) OJ No. L 215, 24.8.1993, p. 1.

increase the maximum price 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 that maximum price shall be made in writing and shall—

(a) specify the health service medicine in respect of which the application is made,

(b) state the reasons for the application, and

be accompanied by the information specified in Schedule 1 to these Regulations.

(3) On an application under this regulation, the Secretary of State shall, subject to paragraphs (4) and (5), reply to the manufacturer or supplier within 90 days of his receipt of that application or, if the Secretary of State gives notice to the manufacturer or supplier that the information is inadequate, within 90 days of the Secretary of State's receipt of such additional information as the Secretary of State may in the notice require.

(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 so 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, or if he has required additional information under paragraph (3), not later than 150 days after the receipt of such additional information.

Application of Regulations

5. These Regulations shall not apply—

(a) at any time to a manufacturer or supplier to whom at the time a voluntary scheme applies;

(b) to a supply of any medicine which is listed in Schedule 10 to the National Health Service (General Medical Services) Regulations 1992(**6**).

Information

6.—(1) Any manufacturer or supplier who supplies branded health service medicines shall—

(a) keep for a minimum period of 3 years from the date of the sale of a branded health service medicine a record of the sales of each presentation of it, including—

(i) information on the number of units of each presentation which are sold for health service purposes, and

(ii) the income derived from sales of that presentation;

for each period of 3 months beginning on 14th February 2000;

(b) retain for a minimum period of 3 years from the date of the sale of a branded health service medicine any information which is in his possession of the kind mentioned above in respect of the period of 3 months starting on 14th February 1999 and each subsequent period of 3 months in that year; and

(c) comply within 14 days, or such longer period as the Secretary of State may allow, with any direction made by the Secretary of State which requires the provision to him of information from that record.

(2) If the Secretary of State is of the opinion that in order to implement these Regulations more information is required than that required under paragraph (1), he may direct the manufacturer or supplier in question to supply that additional information within 14 days or such longer period as he may allow.

(**6**) S.I.1992/635; the relevant amending instruments are S.I.s 1992/2412, 1993/2421, 1994/2620, 1995/3093 and 1997/981.

(3) Where the Secretary of State directs the supply of additional information under paragraph (2), he shall at the time of giving that direction also give written notice to the manufacturer or supplier (as the case may be) of the reason why the additional information is required.

Enforcement

7.—(1) Any person who supplies a branded health service medicine for health service purposes at a price in excess of that permitted under these Regulations shall be liable, on the demand of the Secretary of State, to pay to him a recoverable sum calculated under Schedule 2 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(**7**) 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.

(4) Where for a continuous period a product is sold at a price in excess of the maximum price, a contravention occurs—

(a) on the date on which that period begins; and

(b) on the completion of every second month during that period.

Penalties

8.—(1) A manufacturer or supplier who fails to comply with a direction made under regulation 6(1)(c) or (2) shall, on the demand of the Secretary of State, pay to him a penalty calculated under Schedule 3 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 penalty calculated up to the date of the demand and the period within which it shall be paid.

Appeals

9. A manufacturer or supplier of branded health service medicines shall have a right of appeal in accordance with regulations made under section 37(5) of the Health Act 1999 against any decision made under these Regulations which relates to him.

Alan Milburn
One of Her Majesty's Principal Secretaries of State

24th January 2000

(**7**) The Monetary Policy Committee was constituted on a statutory basis by section 13 of the Bank of England Act 1998

SCHEDULE 1

Regulation 4(2)

FINANCIAL INFORMATION

1. Audited accounts for the latest accounting year for which audited accounts are available including the figures showing for that year in respect of branded health service medicines—

(a) the sales for health service purposes;

(b) any sales 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.

2. 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 1, showing the information of the kind required under that paragraph.

SCHEDULE 2

Regulation 7(1)

RECOVERABLE SUMS

1. For the purposes of regulation 7, the recoverable sum shall be the sum of—

(a) the difference between the amount which a person would have received had the product been sold at the maximum price and the amount that he 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 Column (1)	*Additional Percentage* 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

SCHEDULE 3

Regulation 8(1)

PENALTIES

1. The daily penalty payable by a manufacturer or supplier who fails to comply with a direction made under regulation 6(1)(c) or (2) shall be determined by reference to—

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

(b) the amount specified in column (2) opposite that entry in respect of each day of the contravention which falls within the period of 14 days which begins on the first day of that contravention; and

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

THE TABLE

National health service sales of manufacturer or supplier	*Daily penalty for first 14 days*	*Daily penalty for subsequent days*
Column (1)	Column (2)	Column (3)
Less than £5 million	£250	£500
Less than £10 million but not less than £5 million	£500	£1,000
Less than £100 million but not less than £10 million	£2,500	£5,000
Not less than £100 million	£5,000	£10,000

2. For the purposes of this Schedule, national health service sales shall be calculated by reference to the amount reimbursed by the Prescription Pricing Authority in the most recent period of 12 months for which information is available.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which apply to the United Kingdom, control the price of branded medicines sold for national health service purposes. They apply only to medicines in respect of which marketing authorisations have been granted (regulation 2) that are supplied by companies which are not scheme members within the meaning of Section 33(4) of the Health Act 1999 (see paragraph 4 below).

The maximum price for such medicines is based on the "initial price" which is defined in regulation 2(1) as the price published by the Department of Health on the internet site www.doh.gov.uk/pprsjuly.htm on 20th January 2000. The maximum price is either the initial price determined by reference to the level of sales for NHS use or a proportion of that price. This level of sales is defined by reference to the sum reimbursed by the PPA in the year ending 30th September 1999. If the sum exceeds £1,000,000 then the maximum price is 95.5 per cent of the initial price: otherwise it is the initial price (regulation 3).

Provision is made for the maximum price to be increased (regulation 4).

These Regulations apply only to those companies which are not members of a voluntary price regulation scheme. The present scheme, agreed on 19th July 1999 between the Department of

Health and the Association of the British Pharmaceutical Industry, introduces an overall 4.5 per cent reduction in the prices of branded medicines used by the NHS. Copies may be obtained from the Department of Health, Room 130, Richmond House, 79 Whitehall, London SW1A 2NS (regulation 5(a)).

Medicines listed under Schedule 10 to the National Health Service (General Medical Services) Regulations 1992, which are therefore not generally used within the NHS, are excluded (regulation 5(b)).

Information on the sales of branded health service medicines is required to be kept, and where the Secretary of State so directs, supplied to him (regulation 4 and Schedule 1).

Provision is also made for enforcing the Regulations and paying interest on outstanding payments (regulation 7 and Schedule 2), the recovery of penalties and excess sums (regulation 8 and Schedule 3) and appeals (regulation 10).

A Regulatory Impact Assessment has been prepared and copies may be obtained from the Department of Health, Room 130, Richmond House, 79 Whitehall, London SW1A 2NS. A copy has also been placed in the Library of each of the Houses of Parliament.