STATUTORY INSTRUMENTS

2000 No. 1763

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

The Health Service Medicines (Control of Prices of Specified Generic Medicines) Regulations 2000

Made - - - -	*6th July 2000*
Laid before Parliament	*6th July 2000*
Coming into force - -	*3rd August 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, after consultation pursuant to sections 34(1) and 36(1) of the Health Act 1999, hereby makes the following Regulations:—

Citation and commencement

1. These Regulations may be cited as the Health Service Medicines (Control of Prices of Specified Generic Medicines) Regulations 2000 and shall come into force on 3rd August 2000.

Interpretation

2.—(1) In these Regulations—

"the list of controlled prices" means the list of prices which was published on the internet at http://www.doh.gov.uk/generics on 6th July 2000 by the Department of Health(**3**);

(**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.
(**3**) Copies printed from the internet may be obtained from Room 130, Richmond House, 79 Whitehall, London SW1A 2NS.

"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 authorisation 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 pack size;

"price", except in the expressions "specified price" and "maximum price", means the actual cost of acquiring a presentation of a specified generic medicine;

"specified generic medicine" means a health service medicine which—

(a) is listed in column (1) of the list of controlled prices notwithstanding the addition of a manufacturer's or supplier's name or trade mark; but

(b) is not identifiable by and traded under a specific name given to it by any person who is the manufacturer, supplier or holder of a marketing authorisation relating to it;

"specified price" in relation to a presentation of a specified generic medicine means the price specified in column (3) of the list of controlled prices opposite the medicine and presentation in question specified in columns (1) and (2);

"supply" means supply by way of sale to a person lawfully conducting a retail pharmacy business or to a registered medical practitioner, in order to enable that person or practitioner (as the case may be) to provide pharmaceutical services within the meaning of—

(a) section 41 of the National Health Service Act 1977(**6**) in England or Wales;

(b) section 27 of the National Health Service (Scotland) Act 1978(**7**) in Scotland; and

(c) article 63 of the Health and Personal Social Services (Northern Ireland) Order 1972(**8**) in Northern Ireland.

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

(3) Any reference in these Regulations to a numbered regulation or Schedule is a reference to a regulation or Schedule 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.

(**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.

(**6**) 1977 c. 49: section 41 was amended by the Health Services Act 1980 (c. 53), sections 1 and 20(1) and Schedule 1, paragraph 53 and Schedule 7; S.I.1985/39; the National Health Service and Community Care Act 1990 (c. 19), Schedule 9, paragraph 18(1) and Schedule 10; the Medicinal Products: Prescription by Nurses etc. Act 1992 (c. 28), Section 2; the Health Authorities Act 1995 (c. 17), Schedule 1, paragraph 29; and the National Health Service (Primary Care) Act 1997 (c. 46), section 41(10) and Schedule 2, paragraph 13. As regards Wales, the functions of the Secretary of State under section 41 were transferred to the National Assembly for Wales under S.I. 1999/672 as amended by the Health Act 1999 (c. 8), section 66.

(**7**) 1978 c. 29: section 27 was amended by the Health Services Act 1980 (c. 53), section 20(2); the National Health Service (Amendment) Act 1986 (c. 66), section 3(3); S.I. 1987/2202; the National Health Service and Community Care Act 1990 (c. 19), Schedule 9, paragraph 19(7); the Medicinal Products: Prescriptions by Nurses etc. Act 1992 (c. 28), section 3 and the National Health Service (Primary Care) Act 1997 (c. 46), Schedule 2, paragraph 44; and is to be read as one with the Health and Medicines Act 1988 (c. 49). The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998 (c. 46).

(**8**) 1972 N.I. 11; amended by S.I. 1997/1177 (N.I. 7).

Control of Prices

3. Subject to regulation 4, the maximum price which is charged by a manufacturer or supplier for the supply of a specified generic medicine for health service use shall not exceed the specified price.

Increases

4.—(1) The Secretary of State may—

(a) on his own motion; or

(b) on an application made in accordance with paragraph (2),

increase the maximum price by direction to specific manufacturers or suppliers of the specified generic medicine.

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

(a) specify the specified generic medicine in respect of which the application is made,

(b) state the reasons for the application.

(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 supplied with the application 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.

Information

5.—(1) Paragraph (2) applies to any manufacturer or supplier of specified generic medicines who holds—

(a) a wholesale dealer's licence within the meaning of section 8(3) of the Medicines Act 1968(**9**); or

(b) a marketing authorisation,

in respect of those specified generic medicines.

(2) Any maufacturer or supplier to whom this paragraph applies shall, to the extent that the information is available to him, comply within 14 days, or such longer period as the Secretary of State may allow, with any direction made by the Secretary of State to list and supply the following information in respect of each specified generic medicine—

(a) the number of packs of each presentation sold, and

(b) the receipts from the sales of each presentation

for the year ending 31st December 1999.

(3) Any manufacturer or supplier who provides information under paragraph (2) which shows total receipts from sales in excess of £1 million shall, by 1st April 2001, list and supply the following

(**9**) 1968 c. 57.

information (in so far as the information is in his possession) in respect of the presentations of specified generic medicines sold in the year ending 31st December 2000—

(a) the number of packs of each presentation sold, and

(b) the receipts from the sales of each presentation.

(4) Where the Secretary of State is of the opinion that in order to implement these Regulations more information is required than that obtained under paragraph (3), 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.

(5) Where the Secretary of State directs the supply of additional information under paragraph (4), 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

6.—(1) Any person who supplies for health service use a specified generic medicine 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 sum calculated under Schedule 1.

(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 sum calculated up to the date of the demand and the period within which it shall be paid.

(3) The 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(**10**) 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

7.—(1) A manufacturer or supplier who fails to comply with a direction made under regulation 5(2) or (3) shall, on the demand of the Secretary of State, pay to him a penalty calculated under Schedule 2.

(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

8. A manufacturer or supplier of specified generic medicines shall have a right of appeal in accordance with regulations made under section 37(5) of the Health Act 1999(**11**) against any decision made under these Regulations which relates to him.

(**10**) The Monetary Policy Committee was constituted on a statutory basis by section 13 of the Bank of England Act 1998 (c. 11).
(**11**) *See* S.I.s 2000/124 and 870.

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

6th July 2000

SCHEDULE 1

Regulation 6

CALCULATION OF PAYABLE SUMS

1. For the purposes of regulation 6, the sum shall be—

(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; plus

(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 2

Regulation 7

PENALTIES

1. The daily penalty payable by a manufacturer or supplier who fails to comply with a direction made under regulation 5(2) or (3) shall be calculated by reference to—

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

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

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

EXPLANATORY NOTE

(This note is part of the Order)

These Regulations, which apply to the United Kingdom, control the price of certain generic medicines which are sold for the purposes of the national health services in England and Wales, Scotland and Northern Ireland (*see* the definition of "health service" in section 38(6) of the Health Act 1999). They apply only to the medicines specified in the list of controlled prices which is published on the web site at the address http://www.doh.gov.uk/generics. Printed copies of the list are available from the Department of Health, Room 130, Richmond House, 79 Whitehall, London SW1A 2NS. Moreover, the Regulations apply only to medicines in respect of which marketing authorisations have been granted (regulation 2).

The maximum price for such medicines is based on the "specified price" which is defined in regulation 2(1) as the price specified in the list of controlled prices. Provision is made for the maximum price to be increased (regulations 3 and 4).

Information on the sales of specified generic medicines is required to be supplied to the Secretary of State (regulation 5).

Provision is also made for enforcing the Regulations and paying interest on outstanding payments (regulation 6 and Schedule 1), the recovery of penalties and excess sums (regulation 7 and Schedule 2) and appeals (regulation 8).

A Regulatory Impact Assessment has been prepared and copies may be obtained also 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.