STATUTORY INSTRUMENTS

2001 No. 3798

NATIONAL HEALTH SERVICE HEALTH AND PERSONAL SOCIAL SERVICES, NORTHERN IRELAND

The Health Service Medicines (Information on the Prices of Specified Generic Medicines) Regulations 2001

Made - - - -	*28th November 2001*
Laid before Parliament	*28th November 2001*
Coming into force - -	*20th December 2001*

The Secretary of State for Health, in exercise of powers conferred by sections 36, 37(1), (2), (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 section 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 (Information on the Prices of Specified Generic Medicines) Regulations 2001 and shall come into force on 20th December 2001.

Interpretation

2.—(1) In these Regulations—

"group of companies" means a holding company and its subsidiary or, where it has more than one subsidiary, each of them and in this definition "subsidiary" has the same meaning as in section 736(1) of the Companies Act 1985(**3**);

"the list of specified generic medicines" means the list of medicines which was published on 20th November 2001 on the internet at http://www.doh.gov.uk/generics/medicines.htm by the Department of Health(**4**);

(**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**) 1985 c. 6, section 736 was substituted by the Companies Act 1989 (c. 40), section 144(1).
(**4**) 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(**5**); 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(**6**);

"presentation" means a particular form of a medicine which may be distinguished from other forms of that medicine by reference to pack size;

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

(a) is included in the list of specific generic medicines notwithstanding the addition of a manufacturer's or supplier's name or trade mark; but

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

"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(**7**) in England or Wales;

(b) section 27 of the National Health Service (Scotland) Act 1978(**8**) in Scotland;

(c) article 63 of the Health and Personal Social Services (Northern Ireland) Order 1972(**9**) in Northern Ireland.

(2) A health service 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 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.

Information

3.—(1) This regulation applies to any manufacturer or supplier of specified generic health service medicines who—

(**5**) 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.

(**6**) OJ No. L 215, 24.8.1993, p. 1.

(**7**) 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: Presciption 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.

(**8**) 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: Prescription 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).

(**9**) 1972 N.I. 11; amended by S.I. 1997/1177 (N.I. 7).

(a) holds either a wholesale dealer's licence within the meaning of section 8(3) of the Medicines Act 1968(**10**) or a marketing authorisation in respect of those specified generic health service medicines; and

(b) during the year ended 31st December 2000 supplied generic medicines for health service use to the value of not less than £1,000,000.

(2) Any holder of a marketing authorisation to whom this regulation applies shall, to the extent that the information is available to him, by 31st January 2002 provide to the Secretary of State the following information in respect of each specified generic health service medicine which was manufactured in accordance with his marketing authorisation during the year ended 31st December 2000—

(a) the number of packs of each presentation sold by way of wholesale or supplied to persons lawfully conducting pharmacy businesses and dispensing doctors, and

(b) the receipts from the sales and supplies of each presentation identified separately in respect of receipts from such sale or supply;

(c) where he did not manufacture the medicines, the identity of the manufacturer and the charges made by him for the manufacture of those medicines;

for the period of 12 months which ended on 31st August 2001.

(3) Any holder of a wholesale dealer's licence to whom this regulation applies shall, to the extent that the information is available to him, by 31st January 2002 provide to the Secretary of State in respect of each specified generic health service medicine information on the number of packs of each presentation—

(a) supplied to persons lawfully conducting pharmacy businesses and dispensing doctors, or

(b) sold by way of wholesale dealing;

together with information on the receipts from the supplies and sales of each presentation identified separately in respect of receipts from supplies to persons conducting pharmacy businesses, supplies to dispensing doctors and sales by way of wholesale dealing for the period of 12 months which ended on 31st August 2001.

(4) Where the manufacture, sale or supply of any medicine mentioned in paragraph (2) or (3) was undertaken by more than one company in a group of companies, the information required in respect of that medicine includes information on transactions between those companies which relate to its manufacture, sale, supply and ownership.

(5) Information given under this regulation shall include information on the amount of any discount or rebate given in respect of each product, or, where discounts and rebates cannot be separately identified, the total value in respect of more than one such product.

Penalties

4.—(1) A manufacturer or supplier who contravenes any provision of regulation 3 shall, on the demand of the Secretary of State, pay to him 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 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.

(**10**) 1968 c. 67 to which there are no relevant amendments.

Appeals

5. A manufacturer or supplier of specified generic health service 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.

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under-Secretary of State,
Department of Health

28th November 2001

(**11**) See S.I. 2000/124 and 870.

THE SCHEDULE Regulation 4

PENALTIES

1. The daily penalty payable by a manufacturer or supplier who contravenes regulation 3 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 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	£1000
Less than £100 million but not less than £10 million	£2500	£5000
Not less than £100 million	£5000	£10000

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 price of specified generic medicines which are supplied for the purposes of the 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).

The definitions in regulation 2 restrict the application of the Regulations. The Regulations apply only to information on medicines specified in the list of medicines which is published on the web site at http://www.doh.gov.uk/generics/medicines.htm. Printed copies of the list are available from the Department of Health, Room 130, Richmond House, 79 Whitehall, London SW1A 2NS. Regulation 2 also contains other definitions.

Regulation 3 requires the provision to the Secretary of State of information on the volume and value of sales by way of wholesale and of supplies to doctors and pharmacists of generic health service medicines.

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

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.