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**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 Supply of
Information) (Amendment) Regulations 2013**

<i>Made</i>	- - - -	<i>6th November 2013</i>
<i>Laid before Parliament</i>		<i>13th November 2013</i>
<i>Coming into force</i>	- -	<i>1st January 2014</i>

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

The Secretary of State has consulted in accordance with sections 261(7), 262, 263(1), 264(1) and 265(9) of that Act.

Citation and commencement

1. These Regulations may be cited as the Health Service Medicines (Control of Prices and Supply of Information) (Amendment) Regulations 2013 and come into force on 1st January 2014.

Amendment of the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007

2.—(1) The Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007(b) are amended as follows.

(2) After regulation 1 (citation and commencement), insert the following regulation—

“Expiry

1A. These Regulations cease to have effect at the end of 31st December 2020.”.

(a) 2006 c.41.

(b) S.I. 2007/1320; the relevant amending instrument is S.I. 2008/3258.

(3) In regulation 2(1) (interpretation), in sub-paragraph (c) of the definition of “branded health service medicine”—

- (a) at the end of paragraph (ii) remove the word “or”,
- (b) at the end of paragraph (iii) insert the word “or”, and
- (c) after paragraph (iii) insert—

“(iv) in relation to Wales, is listed in Schedule 1 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004(a);”.

(4) In regulation 3 (information)—

- (a) in paragraph (1)—

- (i) in sub-paragraph (a), for the words from “subsections (3) and” to “Medicines Act 1968” substitute “regulation 18 (wholesale dealing in medicinal products) of the Human Medicines Regulations 2012(b)”,

- (ii) for sub-paragraph (b) substitute the following sub-paragraph—

“(b) has, during the most recent complete calendar year, supplied branded health service medicines for health service use in the United Kingdom, from which it derived sales income of £5 million or more.”,

- (b) in paragraph (3), for the words “paragraphs (5) and (6)” substitute “paragraphs (5) to (7)”, and

- (c) for paragraphs (5), (6) and (7), substitute the following paragraphs—

“(5) A manufacturer or supplier of branded health services medicines must, 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 paragraphs (6) and (7) 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 supplied by it, and the total number of presentations supplied, to—

- (i) wholesalers;
 - (ii) retail pharmacists;
 - (iii) dispensing doctors who are not GMS contractors or PMS contractors;
 - (iv) GMS contractors;
 - (v) PMS contractors;
 - (vi) health service hospitals;
 - (iv) any other persons or bodies supplied by it with branded health service medicines for health service use; and

- (b) information about discounts given by it, specifying separately discounts given to—

- (i) wholesalers;
 - (ii) retail pharmacists;
 - (iii) dispensing doctors who are not GMS contractors or PMS contractors;
 - (iv) GMS contractors;
 - (v) PMS contractors;
 - (vi) health service hospitals; or
 - (v) any other persons or bodies supplied by it with branded health service medicines for health service use,

(a) S.I. 2004/1022.

(b) S.I. 2012/1916.

which cannot be specifically attributed to a particular presentation.

(6) The information required by paragraph (5) must be supplied—

(a) for—

- (i) the period from 1st January 2014 to 31st August 2014, within 2 months of the end of that period;
- (ii) the period from 1st September 2014 to 31st December 2014, within 2 months of the end of that period; and
- (iii) each subsequent complete calendar year, within 2 months of the end of that year.

(7) Where a manufacturer or supplier is required to provide information to the Secretary of State under this regulation—

- (a) if that manufacturer or supplier is in possession of an audited copy of that information (for example, an extract from audited company accounts), the information in that copy must 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 must provide information to demonstrate how the information has been quality assured.

(8) In this regulation “presentation” means a particular form of a branded health service 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, method of administration or formulation for use in clinical practice.”.

(5) For regulation 4 (penalties), substitute the following regulation—

“Penalties

4.—(1) A manufacturer or supplier of a branded health service medicine who contravenes regulation 3(5), (6) or (7) (information requirements) must, on the demand of the Secretary of State, pay to the Secretary of State a daily penalty calculated under the Schedule to these Regulations.

(2) The daily penalty to be applied is to be calculated as if the manufacturer or supplier’s health service sales were at the highest rate set out in column 1 of the Schedule, if—

- (a) the value of a manufacturer or supplier’s health service sales is not shown in the information that has been supplied under these Regulations; or
- (b) no information has been supplied by the manufacturer or supplier.

(3) A daily penalty which is calculated in accordance with paragraph (2) continues to be payable at the highest rate until the information is supplied.

(4) A demand made under paragraph (1) must 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 must state the amount of the penalty calculated up to the date of the demand and the period within which it must be paid.”.

(6) After regulation 7 (revocation) insert the following regulation—

“Review

8.—(1) Before the end of the 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) “Review period” means the period of seven years beginning on 1st January 2014.”.
- (7) In the Schedule (penalties)—
 - (a) in paragraph 1, for the words “3(5) or (6)” substitute “3(5),(6) or (7) including a manufacturer or supplier or to whom regulation 4(2) applies”, and
 - (b) in paragraph 2, for the words from “the amount recorded by” to the end of that paragraph substitute “its total health service sales in the United Kingdom as shown in its most recent audited accounts or other quality assured information.”.

Amendment of the Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008

3.—(1) The Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008(a) are amended as follows.

- (2) In regulation 1 (citation, commencement and interpretation), in paragraph (2)—
 - (a) for the definition of “presentation” substitute the following definition—
 - ““presentation” means a particular form of a branded health service 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, method of administration or formulation for use in clinical practice;”, and
 - (b) omit the definition of “relevant medicine”.
- (3) After regulation 1, insert the following regulation—

“Expiry

1A. These Regulations cease to have effect at the end of 31st December 2020.”.

- (4) For regulation 2 (control of prices), substitute the following regulation—

“Control of Prices

2.—(1) Subject to paragraph (2) to (4) and regulation 4 (low cost presentations), the maximum price which may be charged for the supply of a presentation is the price at which that presentation was on sale for health service purposes on 1st December 2013 less 15 per cent, without regard to any discount or other variation of the price which did not have general application on that date.

(2) In the calculation of maximum price, the percentage reduction set out in paragraph (1) does not apply 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, from which it derived a sales income of less than £5 million.

(3) This regulation does not apply—

- (a) 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;

(a) S.I. 2008/3258; the relevant amending instrument is S.I. 2012/2791.

- (b) where the presentation has no price on 1st December 2013; or
- (c) where the maximum price for the presentation is otherwise determined by any of the following regulations.

(4) Where the amount determined under paragraph (1) results in an amount which includes a fraction of a penny, the maximum price is rounded down to the nearest whole penny.”.

(5) In regulation 3 (new products), in paragraph (1), for the words from “Where a presentation” to “1st December 2008,” substitute “Where there is no price for a presentation in the United Kingdom on 1st December 2013,”.

(6) For regulation 4 (low cost presentations), substitute the following regulation—

“Low cost presentations

4. If a presentation was on sale for health service purposes on December 1st 2013 for a price of less than £2.00, the maximum price which may be charged for that presentation is the price at which it was on sale for health service purposes on that date, without regard to any discount or other variation of the price which did not have general application on that date.”.

(7) After regulation 10 (revocation) insert the following regulation—

“Review

11.—(1) Before the end of the 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) “Review period” means the period of seven years beginning on 1st January 2014.”.

Revocation

4. The Health Service Branded Medicines (Control of Prices and Supply of Information) Amendment Regulations 2012(a) are revoked.

Signed by authority of the Secretary of State for Health.

6th November 2013

Earl Howe
Parliamentary Under-Secretary of State,
Department of Health

(a) S.I. 2012/2791.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which apply to the United Kingdom, amend the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007 (“the 2007 Regulations”) and the Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008 (“the 2008 Regulations”).

Regulation 2 amends the 2007 Regulations, under which any manufacturer or supplier of a branded health service medicine (both those in the Pharmaceutical Price Regulations Scheme, a voluntary price control scheme for branded medicines scheme and those outside that scheme) must provide information to the Secretary of State. The amendments clarify the information on presentations which must be provided from 1st January 2014 and gradually extends the intervals at which information is to be provided from 3 months to 1 year.

Regulation 2(2) inserts a provision which provides that the 2007 Regulations are to cease to have effect at the end of 2020.

Regulation 2(5) substitutes regulation 4 of the 2007 Regulations and inserts a provision that if a penalty is to be applied, but the value of a manufacturer or supplier’s health service sales is not known, the penalty is calculated using the highest rate set out in Column 1 of the Schedule and remains payable at that rate until the manufacturer or supplier provides the information.

Regulation 2(6) inserts new regulation 8 into the 2007 Regulations. It requires the Secretary of State to review the operation and effect of the 2007 Regulations and publish a report within seven 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 amendment.

Regulation 3 amends the 2008 Regulations, which control the maximum price of presentations that are supplied for the health services use by any manufacturer or supplier who is not a member of the Pharmaceutical Price Regulation Scheme except where regulation 4 applies. The maximum price is the price for that presentation on 1st December 2013 less 15 per cent, but without regard to any discount or other variation of the price which did not have general application on that date.

The percentage reduction element of the maximum price calculation does not apply to suppliers or manufacturers of branded health service medicines for health service use, from which the derived sales income in relation to those health service sales is less than £5 million.

Regulation 3(3) inserts a provision which provides that the 2008 Regulations are to cease to have effect at the end of 2020.

Regulation 3(6) inserts new regulation 4 into the 2008 Regulations. It sets out the maximum price that applies to low cost presentations, which are solely presentations with a price of less than £2.00 and which are exempt from the percentage reduction in regulation 3.

Regulation 3(7) inserts new regulation 11 into the 2008 Regulations. It requires the Secretary of State to review the operation and effect of the 2008 Regulations and publish a report within seven 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 amendment.

Regulation 4 revokes the Health Service Branded Medicines (Control of Price and Supply of Information) Amendment Regulations 2012.

An Impact Assessment has been prepared and is available at www.dh.gov.uk. Copies may also be obtained from the Department of Health, Zone 456D, Skipton House, 80 London Road, London SE1 6LH.

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