STATUTORY INSTRUMENTS

2015 No. 233

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 2015

Made - - - -	*10th February 2015*
Laid before Parliament	*17th February 2015*
Coming into force - -	*9th March 2015*

The Secretary of State for Health makes the following Regulations in exercise of the powers conferred by sections 261(7), 262 to 265, 266(1)(a) 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, 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 2015 and come into force on 9th March 2015.

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(**2**) are amended as follows.

(2) In regulation 2 (interpretation), in sub-paragraph (c)(iv) of the definition of "branded health service medicine", after "in relation to Wales" omit "is".

(**1**) 2006 c.41.
(**2**) S.I. 2007/1320, as amended by S.I. 2008/3258 and S.I. 2013/2881; there are other amending instruments but none is relevant.

(3) In regulation 3 (information)—

(a) for paragraph (2) substitute the following paragraph—

"(2) The obligation to provide information under this regulation and regulation 3A 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 voluntary scheme to provide within the time limits set out in the voluntary scheme such information relating to the sales income in respect of each branded health service medicine as is required by the voluntary scheme.";

(b) omit paragraph (4);

(c) in paragraph (5)(a) for "total number of presentations" substitute "quantity of each presentation"; and

(d) for paragraph (8) substitute the following paragraph—

"(8) In this regulation and regulation 3A—

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

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

(4) After regulation 3 (information) insert the following regulation—

"**Further Information**

3A.—(1) A manufacturer or supplier of branded health service medicines must, in respect of each transaction for each presentation with each purchaser, record and keep, for six years from the date of each transaction, information about—

(a) the sales income actually received; and

(b) the quantity of each presentation sold.

(2) Where the Secretary of State reasonably believes that a manufacturer or supplier of branded health service medicines has breached any of the requirements of these Regulations or the Health Service Branded Medicines (Control of Prices and Supply of Information) (No. 2) Regulations 2008(**3**), the Secretary of State may require that the manufacturer or supplier provide any information required to be kept by virtue of paragraph (1).

(3) A request under paragraph (2) must be in writing and must specify—

(a) the presentations to which the request relates;

(b) the period of time the information must cover; and

(c) such period, which must not be less than 28 days from the date of the written request, as is reasonable in all the circumstances within which the information must be provided."

(5) In regulation 4(1) (penalties), for "regulation 3(5), (6) or (7) (information requirements)" substitute "regulation 3(5) to (7) (information) or regulation 3A (further information)".

(**3**) S.I. 2008/3258; amended by S.I.2013/2881.

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 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 relevant 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 or method of administration or formulation for use in clinical practice;";

(b) after the definition of "presentation", insert—

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

(3) in regulation 2 (control of prices) in paragraph (3)—

(a) omit "or" at the end of paragraph (b);

(b) insert "or" at the end of paragraph (c); and

(c) insert the following paragraph after paragraph (c)—

> "(d) to any presentation which was procured under one or more framework agreements under the Public Contracts Regulations 2006(**4**)—
>
> (i) where the framework agreement was entered into on or before 31st December 2013 or was entered into following a tender which closed on or before 31st December 2013, and
>
> (ii) until the day after the day at the end of which the relevant framework agreement expires.".

Signed by authority of the Secretary of State for Health.

George Freeman
Parliamentary Under-Secretary of State
Department of Health

10th February 2015

(**4**) S.I. 2006/5 to which there are amendments not relevant to these Regulations.

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 a manufacturer or supplier of a branded health service medicine that is not a member of the Pharmaceutical Price Regulation Scheme must provide information to the Secretary of State.

Regulation 2(2) corrects a typographical error in the 2007 Regulations.

Regulation 2(3)(a) and 2(3)(b) disapplies the information requirements to manufacturers or suppliers who have joined the Pharmaceutical Price Regulation Scheme.

Regulation 2(3)(c) clarifies that manufacturers must provide information on the quantity of each presentation.

Regulation(3)(d) amends the definition of "presentation" so that it only includes a relevant medicine. A relevant medicine means a medicine which is both a prescription only medicine and a branded health service medicine.

Regulation 2(4) inserts a provision which requires manufacturers and suppliers to record and keep specified information on the sale of their presentations. The Secretary of State may request this information if he believes that the relevant manufacturer or supplier has breached the 2007 Regulations or the 2008 Regulations.

Regulation 2(5) enables the Secretary of State to demand a penalty in the circumstances where a manufacturer or supplier breaches any of the information requirements in the 2007 Regulations.

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.

Regulation 3(2) amends the definition of "presentation" so that it only includes a relevant medicine.

Regulation 3(3) states that the percentage reduction element of the maximum price calculation in regulation 2 of the 2008 Regulations does not apply to any presentation which was procured under one or more framework agreements under the Public Contracts Regulations 2006 where the framework agreement was entered into on or before 31st December 2013 or was entered into following a tender which closed on or before 31st December 2013 and until the day after the day at the end of which the relevant framework agreement expires.

The Impact Assessment has been prepared and is available at https://www.gov.uk/government/consultations/branded-medicines-controlling-prices. Copies may also be obtained from the Department of Health, Wellington House, 133-155 Waterloo Road, London, SE1 8UG.