STATUTORY INSTRUMENTS

2013 No. 2881

The Health Service Medicines (Control of Prices and Supply of Information) (Amendment) Regulations 2013

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(**1**) 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;

(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.

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

(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.".