NATIONAL HEALTH SERVICE, ENGLAND AND WALES

The Branded Health Service Medicines (Costs) Regulations 2017

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

The Secretary of State has consulted in accordance with sections 262(1), 263(1), 264(1), 264C(1) and 265(9) of the National Health Service Act 2006.

Citation, Commencement and Interpretation

1.—(1) These Regulations may be cited as the Branded Health Service Medicines (Costs) Regulations 2017 and shall come into force on [date].
   (2) In these Regulations—
       “the 1978 Act” means the National Health Service (Scotland) Act 1978(b);

(a) 2006 c.41.
(b) 1978 c.29.
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“the 2006 Act” means the National Health Service Act 2006;
“the 2006 Wales Act” means the National Health Service (Wales) Act 2006(a);
“the 1972 Order” means the Health and Personal Social Services (Northern Ireland) Order 1972(b);
“Accounting Reference Period” has the meaning given to it under section 391 of the Companies Act 2006(c);
“common name” means the non-propriety name or if one does not exist, the usual common name;
“dispensing doctor” is to be construed in accordance with regulation 89 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(d);
“final quarter” means the last quarter in a Financial Year;
“Financial Year” has the meaning given to it under section 390 of the Companies Act 2006;
“GMS contractor” means a person providing primary medical services under a general medical services contract made under—
(a) section 84 (general medical services contracts; introductory) of the 2006 Act in relation to England;
(b) section 42 (general medical services contracts; introductory) of the 2006 Wales Act in relation to Wales;
(c) section 17J (health boards power to enter into general medical services contracts) of the 1978 Act in relation to Scotland; or
(d) article 57 of the 1972 Order in relation to Northern Ireland;
“health service hospital” means a hospital owned or managed by a health service body;
“health service body” means—
(a) a Special Health Authority, National Health Service Trust or NHS foundation trust established or continued under the 2006 Act;
(b) a Local Health Board established or constituted under the 2006 Wales Act;
(c) a Health Board or Special Health Board constituted under section 2 (Health Boards and Special Health Boards) of the 1978 Act(e);
(d) a Health and Social Services Board established under the 1972 Order;
(e) a special health and social services agency established under the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990;
(f) the Common Services Agency for the Scottish Health Service constituted under section 10 (Common Services Agency) of the 1978 Act(f);
(g) the Northern Ireland Central Services Agency for the Health and Social Services established under the 1972 Order; or
(h) a Health and Social Services trust established under the Health and Personal Social Services (Northern Ireland) Order 1991;

(a) 2006 c.42.
(b) S.I. 1999/11.
(c) 2006 c.46.
(d) S.I. 2013/349.
(e) 1978 c.29; section 2 was amended by section 28, section 66(1), Schedule 9, paragraph 19(1) and Schedule 10, paragraph 1 of the National Health Service and Community Care Act 1990 (c.19), section 14(2) of and Schedule 7, paragraph 1 to the health and social services and Social Security Adjudications Act 1983 (c.41), Schedule 2, paragraph 2(2) to the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13), Schedule 1, paragraph 1(2)(b) to the National Health Service Reform (Scotland) Act 2004 (asp 7), and section 2(1) of the Health Boards (Membership and Elections) (Scotland) Act 2009 (asp 5).
(f) 1978 c.29; section 10 was amended by Schedule 6, paragraph 2 to the Health Services Act 1980 (c.53), section 66(2) of and Schedule 10, paragraph 1 to the National Health Service and Community Care Act 1990 (c.19), Schedule 4, paragraph 44 to the Health Act 1999, Schedule 2, paragraph 2 to the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13), and Part 2, section 63 of the Public Bodies (Joint Working) (Scotland) Act 2014 (asp 9).
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“manufacturer or supplier” means a manufacturer or supplier of presentations;
“marketing authorisation” has the meaning given by regulation 8(1) of the Human Medicines Regulations 2012(a);
“new manufacturer or supplier” means a manufacturer or supplier that is within its first Accounting Reference Period;
“NHS chemist” means a person who is an NHS chemist or LPS chemist within the meanings given in regulation 2 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013;
“non-propriety name” means a name which is, or which is a permitted variation of—
(a) an International Non-propriety Name (INN);
(b) an International Non-propriety Name Modified (INNM);
(c) a British Approved Name (BAN);
(d) a British Approved Name Modified (BANM); or
(e) an approved name
and for this purpose these names (and their permitted variations) have the same meanings as in a list of names which has been prepared and caused to be published in accordance with regulation 318 of the Human Medicines Regulations 2012(b) (list of names) and which is in force;
“other payments” includes royalties;
“paid” means monies which have been received and cleared by the Department of Health on the fourth full working day after the electronic transfer by the payee;
“pharmaceutical services” means pharmaceutical services within the meaning of—
(a) section 126 (arrangements for pharmaceutical services) of the 2006 Act in England;
(b) section 80 (arrangements for pharmaceutical services) of the 2006 Wales Act in Wales;
(c) section 27 (arrangements for provision of pharmaceutical services) of the 1978 Act in Scotland;
(d) section 63 (arrangements for pharmaceutical services) of the 1972 Order in Northern Ireland;
“PMS contractor” means a person providing primary medical services under—
(a) a personal medical services agreement made under section 92 (arrangements by the Board(c) for the provision of primary medical services) in relation to England;
(b) an agreement made under section 50 (arrangements by Local Health Boards for the provision of primary medical services) of the 2006 Wales Act in relation to Wales;
(c) an agreement made under section 17C (personal medical or dental services) of the 1978 Act in relation to Scotland; or
(d) a personal medical services agreement made under article 15B (provision of primary medical services or personal dental services) of the 1972 Order in relation to Northern Ireland;
“prescription only medicine” is to be construed in accordance with regulation 5 of the Human Medicines Regulations 2012;
“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;

(a) S.I. 2012/1916
(b) S.I. 2012/1916
(c) See section 1H of the 2006 Act.
“quarter” means, in relation to a Financial Year which is of at least three months duration, the three month period beginning on the first day of the Financial Year, and every subsequent three month period in that year;

“relevant medicine” means a health service medicine—

(a) to which a brand name has been applied that enables the product to be identified without reference to the common name;

(b) which is a medicinal product in respect of which a marketing authorisation has been granted;

(c) which is a prescription only medicine; and

(d) which is not—

(i) in relation to England, listed in Schedule 1 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004(a);

(ii) in relation to Scotland, specified in any directions given by the Scottish Ministers under section 17N(6) (other mandatory contract terms) of the 1978 Act(b) as being drugs, medicines or other substances which may not be ordered by a GMS contractor made under section 17J for patients in the provision of primary medical services under a general medical services contract made under section 17J (health boards power to enter into general medical services contracts) of the 1978 Act(c) in relation to Scotland;

(iii) in relation to Northern Ireland, listed in Schedule 1 to the Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc.) Regulations (Northern Ireland) 2004(d); or

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

“remaining period” means—

(a) in relation to a Financial Year which is of less than three months’ duration, the entire Financial Year(f);

(b) in relation to a Financial Year which is more than three months’ duration, any part of that Financial Year, which cannot be more than three months, falling after the final quarter;

“sales report” means a report made in accordance with the requirements of regulation 25;

“small manufacturer or supplier” means a manufacturer or supplier that has received in respect of presentations, sales income below the thresholds set out in column (2) of the table in Schedule 2 where it satisfies the corresponding description of the manufacturer’s or supplier’s Accounting Reference Period in column (1) of that table;

“statutory audited accounts” means accounts prepared in accordance with section 394 of the Companies Act 2006 and audited in accordance with Part 16 of the Companies Act 2006;

“supply” means supply by way of sale;

“voluntary scheme” means a scheme referred to in section 261(1) of the 2006 Act; and

“wholesaler” means a person who—

(a) is a holder of a wholesale dealer’s licence within the meaning of regulation 18 (wholesale dealing in medicinal products) of the Human Medicines Regulations 2012; and

(a) S.I. 2004/629.
(b) 1978 c. 29; section 17N was inserted by section 4 of the Primary Medical Services (Scotland) Act 2004 (asp1).
(c) 1978 c. 28; section 17J was inserted by section 4 of the Primary Medical Services (Scotland) Act 2005 (asp 1).
(d) S.I. 2004/142.
(e) S.I. 2004/1022.
(f) Sections 390, 391 and 392 of the Companies Act 2006 provide that a company can have a Financial Year of any period between 1 day up to a maximum of 18 months, plus or minus seven days.
(b) is not a retail pharmacist, dispensing doctor, GMS contractor or PMS contractor nor is a health service hospital.

Expiry

2. These Regulations cease to have effect at the end of 7 years after the coming into force date.

Application

3. These Regulations do not apply to a manufacturer or supplier to whom, at the time of supply, a voluntary scheme applies.

PART 1
PAYMENT SCHEME

Payment Scheme

4.—(1) The persons listed in paragraph (2) must, in accordance with this regulation and Schedule 1, pay to the Secretary of State \[x\] per cent of their sales income received in respect of their presentations.

(2) The persons are—

(a) a manufacturer or supplier holding the marketing authorisation for a presentation;

(b) any other manufacturer or supplier with sales income in respect of presentations specified in a direction given by the Secretary of State.

(3) Where paragraph (2)(b) applies, the direction must specify the date (which must not be earlier than 28 days from the date of the direction) from which the provisions of this regulation start to apply to the manufacturer or supplier.

(4) This regulation does not apply to a small manufacturer or supplier, as determined in accordance with Schedule 2, or a new manufacturer or supplier.

New Manufacturers and Suppliers

5.—(1) The persons listed in paragraph (2) must, in accordance with this regulation and Schedule 2, pay to the Secretary of State \[x\] per cent of their sales income received in respect of its presentations.

(2) The persons are—

(a) a new manufacturer or supplier holding the marketing authorisation for a presentation;

(b) any other new manufacturer or supplier with sales income or estimated sales income in respect of presentations specified in a direction given by the Secretary of State.

(3) Where paragraph (2)(b) applies, the direction must specify the date (which must not be earlier than 28 days from the date of the direction) from which the provisions of this regulation start to apply to the new manufacturer or supplier.

Enforcement of Recoverable Sum

6.—(1) Any manufacturer or supplier who fails to make the payment required by regulations 4 or 5 will be liable, on the demand of the Secretary of State, to pay him a recoverable sum calculated in accordance with Schedule 5 to these Regulations.

(2) In determining the recoverable sum due under paragraph (1) the Secretary of State may reasonably take into account any information relating to medicinal products, whether or not the Secretary of State obtained that information under these Regulations.
(3) A demand made under paragraph (1) must be made by a notice in writing addressed to the manufacturer or supplier in question and must state—

(a) the quarter, quarters or remaining period to which the recoverable sum relates;
(b) the amount of the recoverable sum calculated from the date when payment was due up to the date of the demand;
(c) the period within which it must be paid; and
(d) the manufacturer’s or supplier’s appeal rights.

**Interest Payable on Late Payment of the Recoverable Sum**

7.—(1) Where the whole or any part of the recoverable sum notified to the manufacturer or supplier is not paid in accordance with a notice under regulation 6, the manufacturer or supplier will be liable to pay to the Secretary of State interest, calculated in accordance with paragraph (2), on the amount of the recoverable sum which remains unpaid.

(2) The interest payable under paragraph (1) shall be simple interest calculated from day to day on the unpaid amount from the date by which the amount is required until the date when payment is made at a rate of 2.5 per cent per annum over the Bank of England base rate from time to time.

(3) For the purpose of this regulation the “Bank of England base rate” means—

(a) the rate announced from time to time by the Monetary Policy Committee of the Bank of England as the official dealing rate, being the rate at which the Bank is willing to enter into transactions for providing short term liquidity in the money markets; or

(b) where an order under section 19 of the Bank of England Act 1998(a) (reserve powers) is in force, any equivalent rate determined by the Treasury under that section.

**Penalties**

8.—(1) A manufacturer or supplier who contravenes regulation 6 or 7 must on the demand of the Secretary of State pay to the Secretary of State, a daily penalty calculated in accordance with Schedule 6.

(2) A demand made under paragraph (1) must be made by a notice in writing addressed to the manufacturer or supplier in question and it must state—

(a) the amount of the penalty calculated from the date when payment was due up to the date of the demand;
(b) the period within which it must be paid; and
(c) the manufacturer’s or supplier’s appeal rights.

**PART 2**

**MAXIMUM PRICES**

**Maximum Price**

9.—(1) Subject to paragraph (2), the maximum price which may be charged by a manufacturer or supplier for the supply of a presentation is—

(a) the price at which that presentation was on sale for health service purposes on 1st December 2013 without regard to any discount or variation of the price which did not have general application on that date, or

(b) if the presentation was launched after 1st December 2013 the price at which that presentation was on sale for health service purposes as specified by the Secretary of State

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(a) 1998 c.11
in accordance with regulation 3 of the Health Service Branded Medicines (Control of
Prices and Supply of Information) (No. 2) Regulations 2008(a) without regard to any
discount or variation of the price which did not have general application

and which is now published in respect of that presentation in the [name of list] on the
Department of Health’s website [website link].

(2) Where the price of a presentation launched after 1st December 2013 has not been specified
by the Secretary of State as set out in paragraph (1)(b), the Secretary of State may specify the
maximum price of the presentation by direction to a specific manufacturer or supplier.

(3) Where the Secretary of State has given a direction to a manufacturer or supplier in
accordance with paragraph (2) or regulation 10, 11, 12, 13, 14 or 15 the maximum price is the
price that is stated to be the maximum price in the latest direction given by the Secretary of State.

New Presentation

10.—(1) At least 28 days prior to the date on which a manufacturer or supplier is intending to
launch a new presentation, the manufacturer or supplier must notify the Secretary of State of its
intention to do so.

(2) A notification by a specific manufacturer or supplier to the Secretary of State must be made
in writing and must specify—
   (a) the presentation in respect of which the notification is made;
   (b) the summary of product characteristics;
   (c) the proposed launch date;
   (d) the proposed maximum price; and
   (e) any relevant information under paragraph (5).

(3) Within 28 days of receiving a notification in accordance with paragraph (2), the Secretary of
State must—
   (a) specify the maximum price at which that new presentation may be supplied for the
purposes of the health service by a direction to the manufacturer or supplier, or
   (b) notify the manufacturer or supplier that more information is required and, where further
information is required, the Secretary of State must notify the manufacturer or supplier of
his decision within 28 days of receiving that further information.

(4) The Secretary of State may specify the maximum price of a presentation by direction where
in respect of the presentation, a manufacturer or supplier fails to comply with paragraph (1).

(5) The maximum price for a new presentation to which this regulation applies may be
determined by the Secretary of State, having regard, among other things, to the following
factors—
   (a) the expected supplies of the presentation for health service purposes;
   (b) the cost of therapeutically equivalent medicines;
   (c) the cost of the presentation in other markets if it is available elsewhere in the world;
   (d) the cost of manufacture of the presentation;
   (e) the cost of research into, and development of, the presentation;
   (f) whether the presentation consists of or contains a new active substance; and
   (g) the likelihood of the presentation being supplied at a particular price.

(6) In these Regulations “new presentation” means a presentation which at the time of the
notification under paragraph (1) is not listed in the [name of list] referred to in regulation 9 or
specified in a direction made by the Secretary of State under regulation 9(2) or regulations 11 to
15.

(a) S.I. 2008/3258, repealed by the coming into force of regulation 31 of these Regulations.
Exemptions

11.—(1) The Secretary of State may, whether or not he receives an application for an exemption from a manufacturer or supplier of a presentation, by direction, exempt for such period as he may determine a presentation from the effect of regulation 9(1) where he considers that an exemption is necessary to ensure adequate supplies of that presentation for health service purposes.

(2) The Secretary of State must specify in any direction made under paragraph (1)—

(a) the new temporary maximum price at which that presentation may be supplied for the purposes of the health service; and

(b) the period during which the new temporary maximum price will apply.

Increases

12.—(1) The Secretary of State may either—

(a) on their own motion; or

(b) on application made under paragraph (2)

increase the maximum price of a presentation by direction to a specific manufacturer or supplier.

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

(a) specify the presentation in respect of which the application is made;

(b) state the reasons for the application;

(c) specify the proposed increased maximum price; and

(d) be accompanied by the information specified in paragraph (6).

(3) Subject to paragraphs (4) and (5), within 90 days of receiving an application made in accordance with paragraph (2), the Secretary of State must notify the applicant—

(a) of their decision; or

(b) that more information is required and, where further information is required, the Secretary of State will notify the applicant of their decision within 90 days of receiving that further information.

(4) Where the number of applications received by the Secretary of State makes it impracticable for the Secretary of State to reply to all or any of the applications within either of the 90 day periods mentioned in paragraph (3), the Secretary of State must notify the applicant before the end of that period.

(5) In a case where the Secretary of State has given notice under paragraph (4) the Secretary of State must make a decision not later than 60 days after the expiry of the 90 day period from receipt of the application, or if the Secretary of State requires further information under paragraph (3), not later than 150 days after the receipt of that further information.

(6) An application made under paragraph (2) must include—

(a) in respect of the presentation for which an increase of maximum price is requested (“the presentation”—

(i) information for the latest complete Financial Year, or where the application is made by a new manufacturer or supplier, information up to the latest complete month in the current Financial Year, setting out—

(aa) the number of supplies of that presentation;

(bb) the total sales income of that presentation;

(cc) any manufacturing and supply costs;

(dd) any research and development costs;

(ee) any non-recurring operational costs; and
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(ff) any other costs;

(ii) estimates of accounts for the two Financial Years which follow the most recent one in respect of which accounts are required to be provided under paragraph (6)(a)(i), showing the information of the kind required under that paragraph.

(b) in respect of total presentations—

(i) information for the latest complete Financial Year, or where the application is made by a new manufacturer or supplier, information up to the latest complete month in the current Financial Year, setting out—

(aa) total sales income;

(bb) any manufacturing and supply costs;

(cc) any research and development costs;

(dd) any non-recurring operational costs; and

(ee) any other costs;

(ii) estimates of accounts for the two Financial Years which follow the most recent one in respect of which accounts are required to be provided under paragraph (6)(b)(i), showing the information of the kind required under that paragraph.

(7) Information supplied under paragraph (6) must be accompanied by a written declaration of approval referred to in regulation 27.

(8) In determining whether to increase the maximum price for a presentation under this regulation, the Secretary of State may have regard to, amongst others, the following factors—

(a) the cost of therapeutically equivalent medicines;

(b) the cost of the presentation in other markets if it is available elsewhere in the world;

(c) the clinical need for the medicines;

(d) manufacturing and supply costs;

(e) research and development costs;

(f) any other costs;

(g) the price which would meet the manufacturer’s or supplier’s total costs for that presentation;

(h) the likelihood of the presentation being supplied at a particular price;

(i) the total sales income in respect of the presentation after deduction of the costs referred to in paragraph (6)(a) over a three year period if the presentation was supplied at its current maximum price;

(j) the total sales income in respect of the presentation after deduction of the costs referred to in paragraph (6)(a) over a three year period if the presentation was supplied at the proposed increase in maximum price; and

(k) the total sales income of the manufacturer’s or supplier’s total presentations after deduction of the costs referred to in paragraph (6)(b) over a three year period.

Decreases

13.—(1) The Secretary of State may, on application made by a manufacturer or supplier, decrease the maximum price of a presentation by direction to a specific manufacturer or supplier.

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

(a) specify the presentation in respect of which the application is made;

(b) state the reasons for the application; and

(c) specify the proposed reduced maximum price.
(3) Subject to paragraphs (4) and (5), within 90 days of receiving an application made in accordance with paragraph (2), the Secretary of State must notify the applicant—

(a) of their decision; or

(b) that more information is required and, where further information is required, the Secretary of State will notify the applicant of their decision within 90 days of receiving that further information.

(4) Where the number of applications received by the Secretary of State make it impracticable for the Secretary of State to reply to all or any of the applications within the 90 day period, the Secretary of State will notify the applicant before the end of that period.

(5) In a case where the Secretary of State has given notice under paragraph (4) the Secretary of State will make a decision not later than 60 days after the expiry of the 90 day period from receipt of the application, or if the Secretary of State requires further information under paragraph (3), not later than 150 days after the receipt of that further information.

Errors

14.—(1) The Secretary of State may either—

(a) on their own motion; or

(b) on application made by a manufacturer or supplier change the maximum price of a presentation by direction to a specific manufacturer or supplier if the Secretary of State considers that the price of a presentation listed in [name of list] is listed in error.

(2) Any direction made under paragraph (1) must specify the new maximum price.

Former Voluntary Scheme Members

15.—(1) Where these Regulations apply to a manufacturer or supplier after they have left the voluntary scheme the maximum price will be the price in the [name of list] as referred to in regulation 9 or as determined by the Secretary of State by direction.

(2) When making a direction under paragraph (1) the Secretary of State may take into account the following factors—

(a) any permanent reductions of price under the voluntary scheme;

(b) any permanent increases of price under the voluntary scheme; and

(c) any other reasonable factors.

Enforcement of Recoverable Sum

16.—(1) Any manufacturer or supplier who supplies a presentation for health service purposes at a price in excess of the maximum price permitted by these Regulations will be liable, on the demand of the Secretary of State, to pay the Secretary of State a recoverable sum calculated in accordance with Schedule 5 to these Regulations.

(2) A demand made under paragraph (1) must be made by a notice in writing addressed to the manufacturer or supplier in question and must state—

(a) the amount of the recoverable sum calculated from the date when payment was due up to the date of the demand;

(b) the period within which it must be paid; and

(c) the manufacturer’s or supplier’s appeal rights.

Interest Payable on Late Payment of the Recoverable Sum

17.—(1) Where any amount of the recoverable sum notified to the manufacturer or supplier is not paid in accordance with a notice under regulation 16, the manufacturer or supplier will be
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liable to pay to the Secretary of State interest, calculated in accordance with paragraph (2), on the amount of the recoverable sum which remains unpaid.

(2) The interest payable under paragraph (1) shall be simple interest calculated from day to day on the unpaid amount from the date by which the amount is required until the date when payment is made at a rate of 2.5 per cent per annum over the Bank of England base rate from time to time.

(3) For the purpose of this regulation the “Bank of England base rate” means—

(a) the rate announced from time to time by the Monetary Policy Committee of the Bank of England as the official dealing rate, being the rate at which the Bank is willing to enter into transactions for providing short term liquidity in the money markets; or

(b) where an order under section 19 of the Bank of England Act 1998 (reserve powers) is in force, any equivalent rate determined by the Treasury under that section.

Penalties

18.—(1) A manufacturer or supplier who contravenes regulation 10(1) must, on the demand of the Secretary of State, pay to the Secretary of State a single penalty not exceeding £100,000.

(2) A manufacturer or supplier who contravenes regulation 9 must, on the demand of the Secretary of State, pay to the Secretary of State a daily penalty calculated under Schedule 6.

(3) A demand made under paragraph (1) or (2) must be made by a notice in writing addressed to the manufacturer or supplier in question and must state—

(a) the amount of the penalty calculated from the date of the contravention up to the date of the demand;

(b) the period within which it must be paid; and

(c) the manufacturer’s or supplier’s appeal rights.

PART 3
INFORMATION REQUIREMENTS

Retention and provision on request of Sales Income Information

19.—(1) A manufacturer or supplier must, in respect of each transaction for each presentation with each buyer or seller, record and keep, for six years from the date of each transaction, information about—

(a) the name of the buyer or seller;

(b) the sales income actually received or the amount actually paid;

(c) the quantity of each presentation sold or bought;

(d) any discounts, rebates or other payments, given or received by the manufacturer or supplier, or to or from any other person or body, in connection with the manufacturing, distribution or supply of that presentation;

(e) any other discounts, rebates of other payments given or received by the manufacturer or supplier to or from the buyer, or any other person or body, in connection with the manufacturing, distribution or supply of relevant medicines, which cannot be specifically attributed to a particular presentation;

(f) the terms on which any discounts, rebates or other payments mentioned in sub-paragraph (d) or (e) were made; and

(g) the names of the other persons or bodies referred to in sub-paragraphs (d) and (e).

(2) Where the Secretary of State reasonably believes that a manufacturer or supplier has breached any of the requirements of these Regulations or requires the information for any of the
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purposes set out at section 264A(4) of the 2006 Act, the Secretary of State may require that a manufacturer or supplier provide the 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 information required;
   (c) the period of time the information must cover; and
   (d) 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.

Regular provision of information

20. Subject to regulation 22, a manufacturer or supplier must provide to the Secretary of State information in accordance with Schedule 4.

 Provision of information for payment scheme

21. Subject to regulations 22 a manufacturer or supplier required to make payments under regulation 4, must provide to the Secretary of State information in accordance with Schedule 1.

Small Manufacturer or Supplier

22.—(1) The obligation to provide information under regulations 20 and 21 does not apply to a small manufacturer or supplier.

   (2) A small manufacturer or supplier must provide to the Secretary of State details of their total sales income in accordance with Schedule 2.

New Manufacturer or Supplier

23. A new manufacturer or supplier required to make payments under regulation 5 must provide to the Secretary of State information in accordance with Schedule 3.

Sales Income

24.—(1) In these Regulations, “sales income” means income from sales after deduction of all trade and other discounts (howsoever named) including settlement discounts, rebates and sales taxes (Value Added Taxes), but before deduction of any payments, including penalties, made under these Regulations.

   (2) Any reference in these Regulations to the calculation of “sales income received in respect of relevant medicines”, including estimates, does not include—

      (a) any presentation which was procured under one or more framework agreement under the Public Contracts Regulations 2006(a) or the Public Contracts Regulations 2015(b)—

         (i) where the framework agreement was entered into on or before [the date of coming into force of the Regulations] or was entered into following a tender which closed on or before [the date of coming into force of the Regulations]; and

         (ii) until the day after the day at the end of which the relevant framework agreement expires.

   (3) Any reference in these regulations to information regarding the calculation of “sales income received in respect of relevant medicines” must identify the framework agreements from which the presentations in paragraph (2) were procured.

(a) S.I. 2006/5
(b) S.I. 2015/102
Sales Report

25.—(1) A “sales report” from the manufacturer or supplier referred to in these Regulations must set out—

(a) the total sales income of the manufacturer or supplier;
(b) the total sales income received in respect of presentations; and
(c) the total payments required from the manufacturer or supplier in accordance with regulations 4 or 5.

Audited Information

26.—(1) In these regulations, “audited sales report” means a sales report prepared and approved by the manufacturer or supplier and audited by the auditor of the company’s statutory accounts or, with the agreement of the Secretary of State, another suitably qualified auditor (“the auditor”) which is accompanied by the information set out in paragraph (2).

(2) The information to accompany the audited sales report is—

(a) a statement from the auditor which includes a statement by the auditor that the audit of the sales report has been carried out in accordance with applicable auditing standards;
(b) the specific applicable auditing standards relied on by the auditor;
(c) a report by an independent auditor and signed by the auditor which provides a reasonable assurance (as provided for in the applicable auditing standards) that the information in the audited annual sales report has not been materially misstated;
(d) the final audit plan prepared in accordance with the applicable auditing standards.

(3) In this regulation “applicable auditing standards” means any relevant International Standard on Auditing and related Statements or Standards produced by the Financial Reporting Council Limited(a).

Written Declaration of Approval

27.—(1) Where a manufacturer or supplier is required under these Regulations to provide information relating to sales income, including estimates, sales reports or audited sales reports or information required by regulation 12, the information must be accompanied by a written declaration of approval from

(a) the director of the manufacturer or supplier; or
(b) where a small manufacturer or supplier, a designated senior official.

(2) For the purposes of paragraph (1)(b) a designated senior official cannot provide a written declaration of approval unless the director or the board of the manufacturer or supplier has provided written authority specifying that the designated senior official has authority to approve the information required under these regulations.

(3) For the purposes of paragraph (1) a director or senior official of a manufacturer or supplier must not approve information unless they are satisfied that the information give a true and fair view of the information required.

Review

28.—(1) If, on review of the audited sales report, and in accordance with paragraph (2), the Secretary of State reasonably believes that a manufacturer or supplier has paid an amount either below or above the amount required by regulations 4 or 5 the Secretary of State may either on their own motion or further to an application made by the manufacturer or supplier determine—

(a) by way of notice that the manufacturer or supplier pay to the Secretary of State; or

(a) Registered Number 02486368.
(b) that the Secretary of State pay to the manufacturer or supplier
the difference between the amount the manufacturer or supplier should have paid had the
payment been made in accordance with regulations 4 or 5 and the amount that the Secretary of
State actually received.

(2) In determining the sum due under paragraph (1) the Secretary of State may reasonably take
into account any information on medicinal products, whether or not the Secretary of State obtained
that information under these Regulations.

(3) A notice made under paragraph (1)(a) must be in writing and must specify—
(a) the quarter, quarters or remaining period to which the payment relates;
(b) the payment sum as calculated under paragraph (1);
(c) such period, which must not be less than 28 days from the date of the notice as is
reasonable in all of the circumstances, within which the payment must be made.

(4) Where a new manufacturer or supplier has provided sales reports in accordance with
paragraphs 5 or 7 of Schedule 3, the Secretary of State may also request an audited sales report to
be provided within 9 months of the last day of the manufacturer’s or supplier’s Financial Year,
where the Secretary of State reasonably considers that this is required to verify the information
that has been provided.

(5) If, on review of the audited sales reports the Secretary of State reasonably believes that a
new manufacturer or supplier had sales of relevant medicines in its first Financial Year of less
than £5million, the Secretary of State must either on their own motion or on application made in
accordance with paragraph (6) pay to the new manufacturer or supplier, the amount the Secretary
of State received for the first Financial Year when the manufacturer or supplier was a new
manufacturer or supplier.

(6) An application made under paragraph (1) or (5) must be made in writing and include the
reasons for the application.

(7) For the purposes of paragraphs (1), (3), (4 or (5), the Secretary of State may request further
information from the manufacturer or supplier.

Penalties

29.—(1) If the Secretary of State reasonably believes that the information provided by a
manufacturer or supplier under this Part is incomplete, he may write to the manufacturer or
supplier to request that further information from the manufacturer or supplier be provided within a
period of 30 days.

(2) In making a determination under paragraph (1), the Secretary of State may take into account
any information on medicinal products, whether or not the Secretary of State obtained
the information under these Regulations.

(3) A manufacturer or supplier who contravenes regulations 19, 20, 21, 22, 23, 24, 25, 26, 27, or
paragraph (1) of this regulation must on the demand of the Secretary of State pay to the Secretary
of State a daily penalty calculated in accordance with Schedule 6 to these Regulations.

(4) Where a manufacturer or supplier has failed to make a payment under regulation 4 or 5, and
failed to provide information under regulations 19, 20, 21, 22 or 23 for the same quarter, quarters
or remaining period, the Secretary of State may make a demand for a penalty under regulation 8 or
this regulation but not under both.

(5) A demand made under paragraph (3) must be made by a notice in writing addressed to the
manufacturer or supplier in question and it must state—
(a) the amount of the penalty calculated up to the date of the demand;
(b) the period within which it must be paid; and
(c) if the manufacturer or supplier has any appeal rights.
Appeals

30. Any manufacturer or supplier in respect of whom the Secretary of State has made an enforcement decision under these Regulations shall have a right of appeal against that decision in accordance with regulations made under section 265(5) of the 2006 Act.

Revocation

31. The Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007(a) and the Health Service Branded Medicines (Control of Prices and Supply of Information) (No. 2) Regulations 2008(b) are revoked.

Annual Review

32. — (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 scheme established by these Regulations;
   (b) assess the extent to which these 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 one year beginning on [date].

Signed by authority of the Secretary of State for Health

Name
Minister of State
Department of Health

(a) S.I. 2007/1320
(b) S.I. 2008/3258
SCHEDULES

SCHEDULE 1

GENERAL PROVISIONS FOR PAYMENT SCHEME

Payment scheme requirements

1. Payments required by regulation 4 must—
   (1) be paid in accordance with table 1 so that they are made within the period specified in column (3) in respect of the period specified in Column (2) which corresponds with the manufacturer’s or supplier’s Accounting Reference Period in column (1); and
   (2) be calculated, where appropriate, in accordance with the rules in paragraphs 3 – 11.

| Table 1 |
|---------------------------------|---------------------------------|---------------------------------|
| Column (1)                      | Column (2)                      | Column (3)                      |
| Length of Current Accounting    | Period to Cover                 | Period within which payment     |
| Reference Period                |                                 | must be made                    |
| Twelve months                   | Each quarter                    | Within 30 days of the last day  |
|                                 |                                 | of each quarter                 |
| Less than twelve months         | Each quarter                    | Within 30 days of the last day  |
|                                 |                                 | of each quarter                 |
|                                 | Any remaining period            | Within 30 days of the last day  |
|                                 |                                 | of the remaining period         |
| More than twelve months         | Each quarter                    | Within 30 days of the last day  |
|                                 |                                 | of each quarter                 |
|                                 | Any remaining period            | As determined by the Secretary  |
|                                 |                                 | of State                        |

Information requirements

2. Information required by regulation 21 must—
   (1) be provided in accordance with table 2 so that the information specified in column (1) must be provided within the period specified in column (3) for the period specified in column (2); and
   (2) be provided, where appropriate, in accordance with the rules in paragraphs 3 – 11.

| Table 2 |
|---------------------------------|---------------------------------|---------------------------------|
| Column (1)                      | Column (2)                      | Column (3)                      |
| Information to be provided      | Period to cover                 | Period within which information |
|                                 |                                 | must be supplied                |
### Illustrative regulations prepared by the Department of Health to accompany the passage of the Health Service Medical Supplies (Costs) Bill through Parliament

<table>
<thead>
<tr>
<th>Sales reports</th>
<th>Each quarter</th>
<th>Within 30 days of the last day of that quarter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales reports</td>
<td>Any remaining period, where the manufacturer’s or supplier’s Accounting Reference Period is less than 12 months</td>
<td>Within 30 days of the last day of the remaining period</td>
</tr>
<tr>
<td>Sales reports</td>
<td>Any remaining period, where the manufacturer’s or supplier’s Accounting Reference Period is more than 12 months</td>
<td>As determined by the Secretary of State</td>
</tr>
<tr>
<td>Audited sales reports</td>
<td>Financial Year</td>
<td>Within 9 months of the last day of the Financial Year.</td>
</tr>
</tbody>
</table>

### Rules

3. Where the rule in paragraph 4 of this Schedule does not apply, the end date of the final quarter of a manufacturer’s or supplier’s Financial Year must be treated as extended or reduced by not more than seven days before or after that quarter, if the end date of the supplier’s or manufacturer’s Financial Year has, in accordance with section 390(2)(b) of the Companies Act 2006, also been reduced or extended by the same period.

4. The end date of the remaining period of a manufacturer’s or supplier’s Financial Year must be treated as extended or reduced by not more than seven days before or after that remaining period, if the end date of the supplier’s or manufacturer’s Financial Year has, in accordance with section 390(2)(b) of the Companies Act 2006, also been reduced or extended by the same period.

5. Where the payment percentage set out in regulation 4 begins to apply to a manufacturer or supplier part way through any of their quarters or remaining period the manufacturer or supplier must, in respect of that quarter or remaining period, calculate the payment and provide the sales report from the date on which the payment percentage in regulation 4 begins to apply until the end of the relevant quarter or remaining period.

6. Where the payment percentage set out in regulation 4 stops applying to a manufacturer or supplier part way through any of their quarters or remaining period, the manufacturer or supplier must, in respect of that quarter or remaining period, calculate the payment and provide the sales report, from the beginning of the quarter or remaining period to the date the payment percentage stopped applying.

7. Where the payment percentage in regulation 4 changes part way through a manufacturer’s or supplier’s quarter or remaining period, the manufacturer or supplier must in respect of that quarter or remaining period, pay the different levels of payment percentage and provide the sales report for the different levels of payment percentage that applied to the sales income during the corresponding part of that quarter or remaining period.

8. Where a manufacturer or supplier changes the length of their current or previous accounting reference date under section 392 of the Companies Act 2006 so as to extend or shorten its current or previous Accounting Reference Period, the new manufacturer or supplier must notify the Secretary of State of the new date of its Accounting Reference Period and provide the Secretary of
Illustrative regulations prepared by the Department of Health to accompany the passage of the Health Service Medical Supplies (Costs) Bill through Parliament

State with the relevant documents which show that the Accounting Reference Period has changed within 30 days of the change.

9. Where a manufacturer or supplier changes the length of their current or previous Accounting Reference Period during their current Accounting Reference Period, the intervals in the Financial Year at which the payments and information will be required and the period within which payment must be made and the information provided will be determined by the Secretary of State.

10. Where the Secretary of State determines the period within which the payments must be made and the information provided, the period must not be less than 28 days.

11. A manufacturer's or supplier’s “previous Accounting Reference Period” means the one immediately preceding its current Accounting Reference Period.
SCHEDULE 2

SMALL MANUFACTURER OR SUPPLIER

Payment scheme requirements

1. Regulation 4 and regulation 21 does not apply to a manufacturer or supplier that has received in respect of presentations, sales income below the thresholds set out in column (2) of the table where it satisfies the corresponding description of the manufacturer’s or supplier’s Accounting Reference Period specified in column (1) of the table.

<table>
<thead>
<tr>
<th>Length of Previous Accounting Reference Period</th>
<th>Column (2) Sales of Relevant Medicines in Financial Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Twelve months</td>
<td>£5million</td>
</tr>
<tr>
<td>Less than twelve months</td>
<td>£5million as proportionately reduced to the number of months in the manufacturer’s or supplier’s Financial Year</td>
</tr>
<tr>
<td>More than twelve months</td>
<td>£5million in the final 12 months of the manufacturer’s or supplier’s Financial Year</td>
</tr>
</tbody>
</table>

Information Requirements

2. A small manufacturer or supplier must provide to the Secretary of State details of the total sales income it received in respect of presentations.

3. The information supplied under paragraph 2 must—
   (a) be supplied for the first complete Financial Year prior to the date on which these Regulations come into force or, if the Regulations start to apply to the manufacturer or supplier after these Regulations come into force, for the first complete Financial Year prior to the date on which these Regulations start to apply to the manufacturer or supplier;
   (b) be supplied within 30 days of the date on which these Regulations come into force or, if the Regulations start to apply to the small manufacturer or supplier after the Regulations come into force, within 30 days of the date on which these Regulations start to apply to the manufacturer or supplier; and
   (c) be supplied for each subsequent complete Financial Year, within 30 days of the end of each Financial Year that the manufacturer or supplier remains a small manufacturer or supplier.

Rules

4. This Schedule must be construed in accordance with the following rules.

5. Where the rule in paragraph 6 does not apply, the end date of the final quarter of a manufacturer’s or supplier’s Financial Year must be treated as extended or reduced by not more
than seven days before or after that quarter, if the end date of the supplier’s or manufacturer’s Financial Year has, in accordance with section 390(2)(b) of the Companies Act 2006, also been reduced or extended by the same period.

6. The end date of the remaining period of a manufacturer’s or supplier’s Financial Year must be treated as extended or reduced by not more than seven days before or after that remaining period, if the end date of the supplier’s or manufacturer’s Financial Year has, in accordance with section 390(2)(b) of the Companies Act 2006, also been reduced or extended by the same period.

7. Where a manufacturer or supplier changes the length of their current or previous accounting reference date under section 392 of the Companies Act 2006 so as to extend or shorten its current or previous Accounting Reference Period, the new manufacturer or supplier must notify the Secretary of State of the new date of its Accounting Reference Period and provide the Secretary of State with the relevant documents which show that the Accounting Reference Period has changed within 30 days of the change.

8. Where a manufacturer or supplier changes the length of their current or previous Accounting Reference Period during their current Accounting Reference Period, the intervals in the Financial Year at which any payments and information will be required and the period within which payment must be made and the information provided will be determined by the Secretary of State.

9. Where the Secretary of State determines the period within which the payments must be made and the information provided, the period must not be less than 28 days.

10. A manufacturer’s or supplier’s “previous Accounting Reference Period” means the one immediately preceding its current Accounting Reference Period.
NEW MANUFACTURER OR SUPPLIER
PAYMENT SCHEME

Payment Requirements

1. Payments required by regulation 5 must—
   (1) be paid in accordance with the table 1 so that in respect of each quarter or remaining period specified in column (2) of a manufacturer’s or supplier’s current Accounting Reference Period specified in column (1), the manufacturer or supplier will make payments no later than within the corresponding time in column (3); and
   (2) be calculated, where appropriate, in accordance with paragraphs 3 – 16.

2. The requirement to make payments under regulation 5 does not apply to—
   (1) a new manufacturer or supplier if their estimate of sales income likely to be received in respect of relevant medicines covering their first Financial Year is less than £5 million and the Secretary of State reasonably believes that the estimate is accurate; or
   (2) a new manufacturer or supplier if, after the first four quarters of their Financial Year, they have extended their Accounting Reference Period and during the first four quarters of the Financial Year, they did not receive £5 million or more in sales income in respect of relevant medicines.

Table 1

<table>
<thead>
<tr>
<th>Column (1)</th>
<th>Column (2)</th>
<th>Column (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of Current Accounting Reference Period</td>
<td>Period to Cover</td>
<td>Period within which payment must be made</td>
</tr>
<tr>
<td>Twelve months</td>
<td>Each quarter</td>
<td>Within 30 days of the last day of each quarter</td>
</tr>
<tr>
<td>Less than twelve months</td>
<td>Each quarter</td>
<td>Within 30 days of the last day of each quarter</td>
</tr>
<tr>
<td></td>
<td>Any remaining period</td>
<td>Within 30 days of the last day of the remaining period</td>
</tr>
<tr>
<td>More than twelve months</td>
<td>Paragraph 3 applies</td>
<td>Paragraph 3 applies</td>
</tr>
</tbody>
</table>

3. Where a new manufacturer or supplier alters their current accounting reference date under section 392 of the Companies Act 2006 so as to extend their Accounting Reference Period they must—
   (1) continue to make payments for the first, second, third and fourth quarter within 30 days of the last day of each quarter; and
   (2) if during the first four quarters they receive sales income in respect of relevant medicines of £5 million or more, continue to make payments for any period after the first four quarters of the
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Financial Year within 30 days of the last day of each quarter and at intervals determined by the Secretary of State for any remaining period.

4. Where a manufacturer or supplier alters their accounting reference date in accordance with section 392 of the Companies Act 2006 so as to extend their previous Accounting Reference Period, and consequently is within their first Accounting Reference Period, the new manufacturer or supplier must—

(1) continue to make any outstanding payments for the first, second, third and fourth quarter within 30 days of the last day of each quarter; and

(2) if during the first four quarters they have received sales income in respect of relevant medicines of £5 million or more, continue to make payments for any remaining period after the first four quarters of the Financial Year within 30 days of the last day of each quarter and at intervals determined by the Secretary of State for any remaining period.

Information requirements

5. A new manufacturer or supplier must provide to the Secretary of State an estimate of the sales income it is likely to receive in respect of relevant medicines for its first Financial Year.

6. Where the estimate of sales income referred to in rule 8 is £5 million or more, the new manufacturer or supplier must in accordance with the rules in paragraphs 3 to 11, provide to the Secretary of State the information in column (1) of table 2 in respect of each corresponding quarter, remaining period or Financial Year specified in column (2) of that table no later than within the corresponding time in column (3) of that table.

Table 2

<table>
<thead>
<tr>
<th>Column (1)</th>
<th>Column (2)</th>
<th>Column (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information to be provided</td>
<td>Period to cover</td>
<td>Period within which information must be supplied</td>
</tr>
<tr>
<td>Sales reports</td>
<td>Each quarter</td>
<td>Within 30 days of the last day of that quarter</td>
</tr>
<tr>
<td>Sales reports</td>
<td>Any remaining period, where the manufacturer’s or supplier’s Accounting Reference Period is less than 12 months</td>
<td>Within 30 days of the last day of the remaining period</td>
</tr>
<tr>
<td>Sales reports</td>
<td>Any remaining period, where the manufacturer’s or supplier’s Accounting Reference Period is more than 12 months</td>
<td>As determined by the Secretary of State</td>
</tr>
<tr>
<td>Audited sales reports</td>
<td>Financial Year</td>
<td>Within 9 months of the last day of the Financial Year.</td>
</tr>
</tbody>
</table>

7. Where the estimate of sales referred to in paragraph 5 is less than £5 million, the new manufacturer or supplier must provide information in accordance with table 3 so that where the length of the Accounting Reference Period specified in column (1) applies, the corresponding
Illustrative regulations prepared by the Department of Health to accompany the passage of the Health Service Medical Supplies (Costs) Bill through Parliament

information specified in column (3) is provided for the period specified in column (2) within the period specified in column (4).

Table 3

<table>
<thead>
<tr>
<th>Column (1)</th>
<th>Column(2)</th>
<th>Column (3) Information to be provided</th>
<th>Column (4) Period within which</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of Accounting Reference Period</td>
<td>Period to cover</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Twelve months</td>
<td>Financial Year</td>
<td>Sales Report</td>
<td>Within 30 days of the last day of the Financial Year</td>
</tr>
<tr>
<td>More than twelve months</td>
<td>Final twelve months of Financial Year</td>
<td>Sales Report</td>
<td>Within 30 days of the last day of the Financial Year</td>
</tr>
</tbody>
</table>

Rules

8. Where the rule in paragraph 9 does not apply, the end date of the final quarter of a manufacturer’s or supplier’s Financial Year must be treated as extended or reduced by not more than seven days before or after that quarter, if the end date of the supplier’s or manufacturer’s Financial Year has, in accordance with section 390(2)(b) of the Companies Act 2006, also been reduced or extended by the same period.

9. The end date of the remaining period of a manufacturer’s or supplier’s Financial Year must be treated as extended or reduced by not more than seven days before or after that remaining period, if the end date of the supplier’s or manufacturer’s Financial Year has, in accordance with section 390(2)(b) of the Companies Act 2006, also been reduced or extended by the same period.

10. Where the payment percentage set out in regulation 5 begins to apply to a manufacturer or supplier part way through any of their quarters or remaining period the manufacturer or supplier must, in respect of that quarter or remaining period, calculate the payment and provide the sales report from the date on which the payment percentage in regulation 5 begins to apply until the end of the relevant quarter or remaining period.

11. Where the payment percentage set out in regulation 5 stops applying to a manufacturer or supplier part way through any of their quarters or remaining period, the manufacturer or supplier must, in respect of that quarter or remaining period, calculate the payment and provide the sales report, from the beginning of the quarter or remaining period to the date the payment percentage stopped applying.

12. Where the payment percentage in regulation 5 changes part way through a manufacturer’s or supplier’s quarter or remaining period, the manufacturer or supplier must in respect of that quarter or remaining period, pay the different levels of payment percentage and provide the sales report for the different levels of payment percentage that applied to the sales income during the corresponding part of that quarter or remaining period.

13. Where a manufacturer or supplier changes the length of their current or previous accounting reference date under section 392 of the Companies Act 2006 so as to extend or shorten its current or previous Accounting Reference Period, the new manufacturer or supplier must notify the Secretary of State of the new date of its Accounting Reference Period and provide the Secretary of State with the relevant documents which show that the Accounting Reference Period has changed within 30 days of the change.

14. Where a new manufacturer or supplier changes the length of their current or previous Accounting Reference Period during their current Accounting Reference Period, the intervals in
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the Financial Year at which the payments and information will be required and the period within which payment must be made and the information provided will be determined by the Secretary of State.

15. Where the Secretary of State determines the period within which the payments must be made and the information provided, the period must not be less than 28 days.

16. A manufacturer's or supplier's “previous Accounting Reference Period” means the one immediately preceding its current Accounting Reference Period.
SCHEDULE 4

GENERAL INFORMATION REQUIREMENTS

1. A manufacturer or supplier must, in accordance with the table, and in accordance with rules 2 to 8 provide to the Secretary of State the information in column (1) for the period specified in column (2), within the period in column (3).

<table>
<thead>
<tr>
<th>Column (1) Information to be provided</th>
<th>Column (2) Period to cover</th>
<th>Column (3) Period within which information must be supplied</th>
</tr>
</thead>
<tbody>
<tr>
<td>The sales income in respect of each presentation supplied by the manufacturer or supplier, and the quantity of each presentation 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; or (vii) any other persons or bodies supplied by it with relevant medicines for health service use.</td>
<td>Financial Year</td>
<td>within 2 months of the last day of the Financial Year</td>
</tr>
<tr>
<td>Any discounts given by the manufacturer or supplier which cannot be specifically attributed to a particular presentation, 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 (vii) any other persons or bodies supplied by it with relevant medicines for health service use.</td>
<td>Financial Year</td>
<td>within 2 months of the last day of the Financial Year</td>
</tr>
<tr>
<td>Statutory audited accounts</td>
<td>Financial Year</td>
<td>within 9 months of the last day of the Financial Year</td>
</tr>
</tbody>
</table>
Illustrative regulations prepared by the Department of Health to accompany the passage of the Health Service Medical Supplies (Costs) Bill through Parliament

Rules

2. This Schedule must be construed in accordance with the following rules.

3. Where the rule in paragraph 4 does not apply, the end date of the final quarter of a manufacturer’s or supplier’s Financial Year must be treated as extended or reduced by not more than seven days before or after that quarter, if the end date of the supplier’s or manufacturer’s Financial Year has, in accordance with section 390(2)(b) of the Companies Act 2006, also been reduced or extended by the same period.

4. The end date of the remaining period of a manufacturer’s or supplier’s Financial Year must be treated as extended or reduced by not more than seven days before or after that remaining period, if the end date of the supplier’s or manufacturer’s Financial Year has, in accordance with section 390(2)(b) of the Companies Act 2006, also been reduced or extended by the same period.

5. Where a manufacturer or supplier changes the length of their current or previous accounting reference date under section 392 of the Companies Act 2006 so as to extend or shorten its current or previous Accounting Reference Period, the new manufacturer or supplier must notify the Secretary of State of the new date of its Accounting Reference Period and provide the Secretary of State with the relevant documents which show that the Accounting Reference Period has changed within 30 days of the change.

6. Where a manufacturer or supplier changes the length of their current or previous Accounting Reference Period during their current Accounting Reference Period, the intervals in the Financial Year at which any payments and information will be required and the period within which payment must be made and the information provided will be determined by the Secretary of State.

7. Where the Secretary of State determines the period within which the payments must be made and the information provided, the period must not be less than 28 days.

8. A manufacturer's or supplier's “previous Accounting Reference Period” means the one immediately preceding its current Accounting Reference Period.
SCHEDULE 5

RECOVERABLE SUMS

1. For the purposes of regulation 6, the recoverable sum will be the sum of—
   (a) the difference between the amount which the Secretary of State should have received in accordance with regulation 6 and the amount that the Secretary of State actually received; and
   (b) the amount calculated by multiplying that difference by the appropriate additional percentage specified in table 1.

2. For the purposes of regulation 16, the recoverable sum will be the sum of—
   (a) the difference between the amount which a person would have received had the product been supplied at the maximum price and the amount that the person actually received; and
   (b) the amount calculated by multiplying that difference by the appropriate additional percentage specified in table 1.

3. In respect of a contravention described in column (1) of the following table, the appropriate additional percentage is specified opposite in column (2).

<table>
<thead>
<tr>
<th>Table</th>
<th>Column (1) Contravention</th>
<th>Column (2) Additional Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>First contravention</td>
<td>5 per cent</td>
<td></td>
</tr>
<tr>
<td>Second contravention</td>
<td>15 per cent</td>
<td></td>
</tr>
<tr>
<td>Third contravention</td>
<td>25 per cent</td>
<td></td>
</tr>
<tr>
<td>Fourth contravention</td>
<td>35 per cent</td>
<td></td>
</tr>
<tr>
<td>Fifth or subsequent contravention</td>
<td>50 per cent</td>
<td></td>
</tr>
</tbody>
</table>

4. For the purposes of this Schedule—
   (a) “second contravention” means in relation to rule 1 of this Schedule, a contravention of regulation 4 or 5 on a second occasion, and in relation to paragraph 2 of this Schedule, a contravention which occurs where a presentation continues to be supplied in contravention of the Regulations for a period of two months after the first contravention which relates to that presentation; and
   (b) each subsequent contravention occurs in relation to paragraph 1 of this Schedule, on the next contravention of regulation 4 or 5, and in relation to paragraph 2 of this Schedule where the same presentation continues to be supplied for a further period of one months from the date of a previous contravention which relates to that product.
SCHEDULE 6

PENALTIES

1. Subject to paragraph 2, the daily penalty payable by a manufacturer or supplier must be calculated by reference to—
   
   (a) the entry in column (1) of table 1 within which the total value of its sales income for branded health service medicines falls;
   
   (b) the amount specified in column (2) opposite that entry in respect of each day of the contravention; and
   
   (c) the amount specified in column (3) opposite that entry in respect of each subsequent day of that contravention.

| Table 1 |
|-----------------|-----------------|------------------|
| **Column (1)**  | **Column (2)**  | **Column (3)**   |
| Total sales income of relevant medicines in most recent complete Financial Year or if a new manufacturer or supplier, total estimate sales income of relevant medicines for first 12 months since date of incorporation | Daily penalty for first 14 days | Daily penalty for subsequent days |
| Less than £100 million | £2,500 | £5,000 |
| £100 million or more | £5,000 | £10,000 |

2. Where the Secretary of State is unable to reasonably determine the sales income specified in the first column of table 1, the daily penalty payable by a manufacturer or supplier must be calculated by reference to—
   
   (a) the manufacturer or supplier’s Total United Kingdom sales in column (1) of table 2;
   
   (b) the amount specified in column (2) opposite that entry in respect of each day of the contravention; and
   
   (c) the amount specified in column (3) opposite that entry in respect of each subsequent day of that contravention.

| Table 2 |
|-----------------|-----------------|------------------|
| **Column (1)**  | **Column (2)**  | **Column (3)**   |
| Total United Kingdom sales | Daily penalty for first 14 days | Daily penalty for subsequent days |
| Less than £100 million | £2,500 | £5,000 |
| £100 million or more | £5,000 | £10,000 |

3. For the purposes of table 2, the total United Kingdom sales of the manufacturer or supplier will be calculated at the time the penalty becomes payable by reference to its total sales in the United Kingdom as shown in its most recent statutory audited accounts.