

**DRAFT REGULATIONS FOR THE PURPOSES OF THE CONSULTATION ON
CHANGES TO THE STATUTORY SCHEME TO CONTROL COSTS OF BRANDED
HEALTH SERVICE MEDICINES**

STATUTORY INSTRUMENTS

2018 No.

**NATIONAL HEALTH SERVICE ENGLAND AND
WALES**

NATIONAL HEALTH SERVICE, SCOTLAND

HEALTH AND SOCIAL CARE, NORTHERN IRELAND

**The Branded Health Service Medicines (Costs) Regulations
2018**

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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), 263(1A), 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 2018 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 2000 Act” means the Freedom of Information Act 2000(a);

“the 2002 Act” means the Freedom of Information (Scotland) Act 2002(b);

“the 2006 Act” means the National Health Service Act 2006;

“the 2006 Wales Act” means the National Health Service (Wales) Act 2006(c);

“the 2009 Act” means the Health and Social Care (Reform) Act (Northern Ireland) 2009(d)

“accounting reference date”, has the meaning given to it under section 391 of the Companies Act 2006(e);

“Accounting Reference Period”, has the meaning given to it under section 391 of the Companies Act 2006;

“common name” means the non-proprietary name or if one does not exist, the usual common name;

“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;

“gross sales income” means income from sales, excluding Value Added Taxes and before deduction of all trade and other discounts (howsoever named) including settlement discounts, rebates or deduction of any payments, including penalties, made under these Regulations;

“health service use” means used to any extent for the purposes of—

- (a) the health service continued under section 1(1) of the 2006 Act;
- (b) health care provided by virtue of the 2009 Act;
- (c) the health service within the meaning of the 1978 Act; or
- (d) the health service continued under section 1(1) of the 2006 Wales Act;

“invented name” is a name which is not the common name and is not liable to be confused with the common name;

“low cost presentation” means a presentation which has a maximum price, as determined by regulation 8, of less than £2.00;

“marketing authorisation” has the meaning given by regulation 8(1) of the Human Medicines Regulations 2012;

“net sales income” means income from sales, excluding Value Added Taxes, and after deduction of all trade and other discounts (howsoever named) including settlement discounts and rebates but before deduction of any payments, including penalties, made under these Regulations;

“new manufacturer or supplier” means a manufacturer or supplier that is within its first Accounting Reference Period;

“NHS chemist” means any person who—

- (a) provides pharmaceutical or local pharmaceutical services under Part 7 of the 2006 Act or as mentioned in section 264A(9) of that Act(f); and
- (b) is not also a primary medical services provider;

“non-proprietary name” means a name which is, or which is a permitted variation of—

- (a) an International Non-proprietary Name (INN);

(a) 2000 c.36.

(b) asp 13.

(c) 2006 c.42.

(d) 2009 c.1

(e) 2006 c.46.

(f) See also section 264A(16), which contains a transitional provision which applies until the coming into force of the repeal of section 27 of the National Health Service (Scotland) Act 1978 by Schedule 3 of the Smoking, Health and Social Care (Scotland) Act 2005 and which relates to the provision of pharmaceutical services in Scotland.

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- (b) an International Non-proprietary Name Modified (INN^M);
- (c) a British Approved Name (BAN);
- (d) a British Approved Name Modified (BAN^M); 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 published under regulation 318 of the Human Medicines Regulations 2012 (list of names) and which is in force;

“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 or method of administration or formulation;

“primary medical services provider” means any person who provides primary medical services (who may be a provider of pharmaceutical services as well as primary medical services) under—

- (a) Part 4 of the 2006 Act;
- (b) Part 4 of the 2006 Wales Act;
- (c) section 2C of the 1978 Act^(a), a contract under section 17J of the 1978 Act^(b) or an agreement under section 17C of the 1978 Act^(c); or
- (d) Part 2 or 6 of the Health and Personal Social Services (Northern Ireland) Order 1972^(d);

“qualified independent auditor” means the auditor of the manufacturer’s or supplier’s statutory audited accounts, or with the agreement of the Secretary of State, another suitably qualified auditor;

“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 medicine to be identified without reference to the common name;
- (b) which is a medicine in respect of which a marketing authorisation has been granted;
- (c) which is a medicine in respect of which a parallel distribution notice^(e) has not been given;
- (d) which is a prescription only medicine; and
- (e) 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^(f);
 - (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^(a) as being

(a) Section 2C was inserted by the Primary Medical Services (Scotland) Act 2004 (asp 1), section 1(2), and has been amended by: the National Health Service Reform (Scotland) Act 2004 (asp 7), Schedule 1, paragraph 1(3); the Tobacco and Primary Medical Services (Scotland) Act 2010 (asp 3), section 37; and SSI 2010/283.

(b) Section 17J was inserted by the Primary Medical Services (Scotland) Act 2004, section 4.

(c) Section 17C was inserted by the National Health Service (Primary Care) Act 1997 (c. 46), section 21(2), and has been amended by: the Primary Medical Services (Scotland) Act 2004, section 2(2); and the Health and Social Care Act 2012 (c. 7), Schedule 21, paragraph 3(2)(a).

(d) S.I. 1972/1265 (N.I. 14).

(e) See Article 57(o) of Regulation 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

(f) S.I. 2004/629.

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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^(b) 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^(c); 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^(d);

“relevant UK hospital” means—

- (a) a UK health service hospital; or
- (b) any other body (not being a public authority) that is responsible, under the arrangements for managing a hospital that supplies UK health service products to patients, for purchasing those health service products;

“remaining period” means—

- (a) in relation to a Financial Year which is of less than three months’ duration, the entire Financial Year^(e);
- (b) in relation to a Financial Year which is of 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 20;

“small manufacturer or supplier” is to be construed in accordance with Schedule 2;

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

“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;

“summary of product characteristics” is to be construed in accordance with regulation 8(1) of the Human Medicines Regulations 2012;

“supply” means supply by way of sale;

“unbranded generic health service medicine” means a health service medicine which includes the non-proprietary name of the medicinal product on the labelling of the product but not an invented name.

“UK health service hospital” means a body which —

- (c) is mentioned in Part 3 of Schedule 1 to the 2000 Act and is responsible, under the arrangements for managing a hospital that supplies UK health service products to patients, for purchasing those health service products; or
- (d) is mentioned in Part 4 of Schedule 1 to the 2002 Act and is responsible, under the arrangements for managing a hospital that supplies UK health service products to patients, for purchasing those health service products;

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

(a) 1978 c. 29; section 17N was inserted by section 4 of the Primary Medical Services (Scotland) Act 2004 (asp1).
(b) 1978 c. 29; section 17J was inserted by section 4 of the Primary Medical Services (Scotland) Act 2005 (asp 1).
(c) S.R. 2004 No.142.
(d) S.I. 2004/1022.
(e) 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.

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“wholesale dealer’s licence” is to be construed in accordance with regulation 18 (wholesale dealing in medicinal products) of the Human Medicines Regulations 2012;

“wholesaler” means a person who—

- (a) is a holder of a wholesale dealer’s licence; and
- (b) is not a primary medical services provider, NHS chemist or UK health service hospital;
and

“written declaration of approval” has the meaning given by regulation 23.

Application

2.—(1) Subject to paragraph (2), these Regulations do not apply to a manufacturer or supplier to whom, at the time of supply, a voluntary scheme applies.

(2) Paragraph (1) does not affect any liability of a person to pay amounts to the Secretary of State arising during a period when the statutory scheme applied to them or the taking of any such action in relation to any such liability.

**PART 1
PAYMENT SCHEME**

Payment scheme

3.—(1) Subject to paragraph (2), any person who is the first manufacturer or supplier in the UK to supply an item of presentation to another person must, in accordance with Schedule 1, pay to the Secretary of State [x per cent] of their net sales income received in respect of any such items of presentation so supplied.

(2) Where the first manufacturer or supplier referred to in paragraph (1) is a new manufacturer or supplier, that manufacturer or supplier must, in accordance with Schedule 3, pay to the Secretary of State [x per cent] of their net sales income received in respect of any such items of presentation so supplied.

(3) Paragraphs (1) and (2) do not apply to the net sales income received in respect of—

- (a) the supply of any item of presentation which was procured under one or more framework agreement under the Public Contracts Regulations 2006(a), the Public Contracts (Scotland) Regulations 2012(b), the Public Contracts Regulations 2015(c) or the Public Contracts (Scotland) Regulations 2015(d)—
 - (i) where the framework agreement was entered into 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 the coming into force of the Regulations];
 - (ii) until the day after the day at the end of which the relevant framework expires;
- (b) any low cost presentations.

(4) This regulation does not apply to a small manufacturer or supplier.

(a) S.I. 2006/5 to which there are amendments not relevant to the Regulations.
(b) SSI 2015/88.
(c) S.I 2015/102 to which there are amendments not relevant to the Regulations.
(d) SSI 2015/446.

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Direction to make a payment

4.—(1) The Secretary of State may give a direction to any manufacturer or supplier not referred to in regulation 3 to pay [x per cent] of their net sales income in respect of an item of presentation where that manufacturer or supplier supplies an item of presentation to another person.

(2) Paragraph (1) does not apply to net sales income received in respect of—

(a) any item of presentation which was procured under one or more framework agreement under the Public Contracts Regulations 2006, the Public Contracts (Scotland) Regulations 2012, the Public Contracts Regulations 2015 or the Public Contracts (Scotland) Regulations 2015—

(i) where the framework agreement was entered into 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 the coming into force of the Regulations];

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

(b) any low cost presentations.

(3) Any direction made under paragraph (1) must specify—

(a) the reason why the manufacturer or supplier has been given a direction under paragraph (1);

(b) the rules with which the manufacturer or supplier must comply with reference to the relevant Schedule of these Regulations; and

(c) the date from which the payments must be made by the manufacturer or supplier.

(4) This regulation does not apply to a small manufacturer or supplier.

Enforcement of recoverable sum

5.—(1) Any manufacturer or supplier who fails to make a payment required by regulations 3 or 4 will be liable, on the demand of the Secretary of State, to pay to the Secretary of State a recoverable sum calculated in accordance with Schedule 4 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

6.—(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 5, 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 as it may be from time to time.

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

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- (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

7.—(1) A manufacturer or supplier who contravenes regulation 5 or 6 must on the demand of the Secretary of State, pay to the Secretary of State, a daily penalty calculated in accordance with Schedule 5.

(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

8.—(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;
- (b) where 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 in accordance with regulation 3 of the Health Service Branded Medicines (Control of Prices and Supply of Information) (No. 2) Regulations 2008(b) without regard to any discount or variation of the price which did not have general application; or
- (c) where the Secretary of State specified the price under regulation 6 of the Health Service Branded Medicines (Control of Prices and Supply of Information) (No. 2) Regulations 2008, the price at which that presentation was on sale for health service purposes as specified by the Secretary of State in accordance with that regulation 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(c).

(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.

(a) 1998 c.11

(b) S.I. 2008/3258 as amended by S.I. 2012/1916, 2013/2881 and 2015/233, repealed by the coming into force of regulation 27 of these Regulations.

(c) [insert website link and physical address]

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(3) Where the Secretary of State has given a direction to a manufacturer or supplier in accordance with paragraph (2) or regulation 9, 10, 11, 12 or 13 the maximum price is the price that is stated to be the maximum price in the latest direction given by the Secretary of State.

(4) Paragraph (1) does not apply to the supply of any item of presentation which was procured under one or more framework agreement under the Public Contracts Regulations 2006 or the Public Contracts (Scotland) Regulations 2012—

- (a) where the framework agreement was entered into before 31st December 2013 or was entered into following a tender which closed on or before 31st December 2013;
- (b) until the day after the day at the end of which the relevant framework expires.

(5) Paragraph (3) does not apply to the supply of any item of presentation which was procured under one or more framework agreement under the Public Contracts Regulations 2006, the Public Contracts (Scotland) Regulations 2012, the Public Contracts Regulations 2015 or the Public Contracts (Scotland) Regulations 2015—

- (a) where the framework agreement was entered into before [the date of the coming into force of these regulations] or was entered into following a tender which closed on or before [the date of the coming into force of these regulations];
- (b) until the day after the day at the end of which the relevant framework expires.

New presentation

9.—(1) At least 60 days prior to the date on which a manufacturer or supplier is intending to place on the market a new presentation, the manufacturer or supplier must notify the Secretary of State of its intention to do so.

(2) A notification under paragraph (1) by a manufacturer or supplier to the Secretary of State must be made in writing and must—

- (a) specify the presentation in respect of which the notification is made;
- (b) specify the summary of product characteristics;
- (c) specify the proposed date for placing on the market the new presentation;
- (d) specify the proposed maximum price; and
- (e) include any relevant information relating to the factors set out under paragraphs (8)(a) to (g).

(3) Within 28 days of receiving a notification in accordance with paragraph (2), the Secretary of State must give the manufacturer or supplier an information notice specifying the additional information required in relation to the factors set out under paragraphs (8)(h) to (i).

(4) Unless further information is required in relation to any of the factors set out under paragraph (8), the Secretary of State must 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 within a period of 28 days of receiving the information requested under paragraph (3).

(5) Where further information is required, the Secretary of State must within 28 days of receiving the information requested in accordance with paragraph (3), notify and where appropriate by giving a further information notice, the manufacturer or supplier that further information is required and inform the manufacturer or supplier of the maximum price within 28 days of receiving that further information.

(6) Where a manufacturer or supplier fails to notify the Secretary of State of its intention to place the presentation on the market within the specified time period or provide the Secretary of State with the information that the Secretary of State requires to determine the maximum price, the Secretary of State may specify the maximum price of that presentation by direction.

(7) Information supplied under this regulation must be accompanied by a written declaration of approval.

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(8) The maximum price for a new presentation to which this regulation applies may be determined by the Secretary of State, having regard to, among other relevant factors, the following factors—

- (a) the clinical need for the new presentation;
- (b) the cost of therapeutically equivalent or comparable medicines to that new presentation;
- (c) the cost of the new presentation in the European Economic Area and any other markets if it is available elsewhere in the world;
- (d) whether the presentation contains a new active substance;
- (e) the date on which the patent protections for each indication of the new presentation expires;
- (f) the total profit of the manufacturer's or supplier's company before interest charges and taxes as set out in the company's statutory accounts;
- (g) the estimated total quantity to be supplied and estimated total net sales income of the new presentation over the period of the first five Financial Years of the manufacturer's or supplier's sales of the new presentation, or where the patent protection period expires before the end of the first five Financial Years, the period until the date of the expiration of the patent protection;
- (h) the reasonableness of the estimated costs of the presentation over the period of the first five Financial Years of the manufacturer's or supplier's sales of the new presentation, or where the patent protection period expires before the end of the first five Financial Years, the period until the date of the expiration of the patent protection, including—
 - (i) manufacturing and supply costs;
 - (ii) research and development costs;
 - (iii) operational costs; and
 - (iv) any other costs;
- (i) the price at which the manufacturer's or supplier's reasonable costs for that presentation, as determined by the Secretary of State would be met.

(9) For the purposes of this regulation, where there is more than one patent protection period, the patent protection period which expires on the latest date will apply.

(10) For the purposes of paragraph (8)(d) a presentation will only be considered to contain a "new active substance", where—

- (a) the European Public Assessment Report published by the European Medicines Agency(a) in relation to the presentation in accordance with Article 13.3 of the Regulation laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency(b) confirms that the presentation contains a new active substance;
- (b) the Assessment Report published by the competent authority of the Member State in relation to the presentation in accordance with Article 21 of the Directive on the Community code relating to medicinal products for human use(c) confirms that the presentation contains a new active substance; or

(a) As established under Regulation 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

(b) Regulation 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

(c) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

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- (c) the Assessment Report published by the licensing authority^(a) in relation to the presentation in accordance with regulation 64(6) of the Human Medicines Regulations 2012 confirms that the presentation contains a new active substance.

(11) In these Regulations “new presentation” means a presentation which at the time the notification under paragraph (2) must be made, is not listed in the [name of list] referred to in regulation 8 or specified in a direction made by the Secretary of State under regulation 8(2) or regulations 10, 11, 12, or 13.

Temporary exemptions

10.—(1) The Secretary of State may by direction, exempt for such period as the Secretary of State may determine a presentation from the effect of regulation 8 where the Secretary of State considers that a temporary 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.

(3) The power to issue a direction under paragraph (1) may be exercised on application by a manufacturer or supplier of a presentation or on the Secretary of State’s own motion.

Increases

11.—(1) The Secretary of State may, on receipt of all of the information required as part of an application made under paragraphs (4) to (7), or on the Secretary of State’s own motion, increase the maximum price of a presentation by direction to a specific manufacturer or supplier.

(2) Unless the number of applications received by the Secretary of State makes it impracticable to do so, the Secretary of State must within 90 days of receiving all of the information required as part of an application made under paragraphs (4) to (7), specify the maximum price at which that presentation may be supplied by direction to a manufacturer or supplier.

(3) 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 the 90 day period, the Secretary of State must notify the specific manufacturer or supplier within the 90 day period and may extend that 90 day period for a further 60 days.

(4) A request 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 request is made;
- (b) state the reasons for the request;
- (c) specify the proposed increased maximum price; and
- (d) include any relevant information relating to the factors set out under paragraph (8)(a), to (f), (g)(i), (g)(ii), (h) and (i).

(5) Within 28 days of receiving the information set out at paragraph (4), the Secretary of State must give the manufacturer or supplier an information notice specifying the additional information required in relation to the factors set out under paragraph (8)(g)(iii) and (g)(iv).

(6) Where further information is required, the Secretary of State must within 28 days of receiving the information under paragraph (5) notify, and where appropriate, by giving an information notice, the manufacturer or supplier that further information is required.

(a) See regulation 6 of the Human Medicines Regulations 2012 for the definition of “licensing authority”.

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(7) Information provided to the Secretary of State under this regulation must be accompanied by a written declaration of approval.

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

- (a) the clinical need for the presentation;
- (b) the likelihood of a supply shortage of that presentation;
- (c) the cost of therapeutically equivalent or comparable medicines to that presentation;
- (d) the cost of the presentation in the European Economic Area and any other markets if it is available elsewhere in the world;
- (e) the date on which the patent protections for each indication of the presentation expires;
- (f) the total profit of the manufacturer's or supplier's company before interest charges and taxes as set out in the company's statutory accounts;
- (g) in respect of the presentation—
 - (i) for the latest complete Financial Year, or where the application is made by a new manufacturer or supplier, up to the latest complete month in the current Financial Year, the total quantity supplied and the total net sales income;
 - (ii) for the five Financial Years which follow the most recent one referred to in subparagraph (g)(i), estimates of the total quantity to be supplied and the total net sales income;
 - (iii) the reasonableness of the estimated costs for the latest complete Financial Year, or where the application is made by a new manufacturer or supplier, the reasonableness of the estimated costs up to the latest complete month in the current Financial Year, including—
 - (aa) manufacturing and supply costs;
 - (bb) research and development costs;
 - (cc) operational costs; and
 - (dd) any other costs;
 - (iv) the reasonableness of the estimated costs over the period of the five Financial Years which follow the most recent one referred to in sub-paragraph (g)(iii), or where the patent protection period expires before the end of the five Financial Years, the period until the date of the expiration of the patent protection from the first Financial Year following the most recent one referred to in subparagraph (g)(iii), including—
 - (aa) manufacturing and supply costs;
 - (bb) research and development costs;
 - (cc) operational costs; and
 - (dd) any other costs;
- (h) in respect of all of the manufacturer's or supplier's presentations—
 - (i) for the latest complete Financial Year, or where the application is made by a new manufacturer or supplier, up to the latest complete month in the current Financial Year, the total quantity supplied and the total net sales income;
 - (ii) for the five Financial Years which follow the most recent one referred to in subparagraph (h)(i), estimates of the total quantity to be supplied and the total net sales income;
 - (iii) the reasonableness of the estimated costs for the latest complete Financial Year, or where the application is made by a new manufacturer or supplier, the reasonableness of the estimated costs up to the latest complete month in the current Financial Year, including—

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- (aa) manufacturing and supply costs;
 - (bb) research and development costs;
 - (cc) operational costs; and
 - (dd) any other costs;
- (iv) the reasonableness of the estimated costs over the period of the five Financial Years which follow the most recent one referred to in sub-paragraph (h)(iii), or where the patent protection period expires before the end of the five Financial Years, the period until the date of the expiration of the patent protection from the first Financial Year following the most recent one referred to in paragraph (h)(iii), including—
- (aa) manufacturing and supply costs;
 - (bb) research and development costs;
 - (cc) operational costs; and
 - (dd) any other costs;
- (v) the price at which the manufacturer's or supplier's reasonable costs for that presentation, as determined by the Secretary of State would be met;
- (vi) the estimated total net sales income after deduction of reasonable costs as determined by the Secretary of State over the most recent complete Financial Year, or where the application is made by a new manufacturer or supplier, up to the latest complete month in the current Financial Year, and the following five Financial Years—
- (aa) if the presentation was supplied at its current maximum price; and
 - (bb) if the presentation was supplied at the proposed increase in maximum price;
- (i) in respect of all of the manufacturer's or supplier's presentations, the reasonable costs as determined by the Secretary of State over the most recent complete Financial Year, or where the application is made by a new manufacturer or supplier, up to the latest complete month in the current Financial Year, and the following five Financial Years.
- (9) For the purposes of this regulation, where there is more than one patent protection period, the patent protection period which expires on the latest date will apply.

Decreases

12.—(1) The Secretary of State may, on receipt of all of the information required as part of an application made by a manufacturer or supplier in accordance with paragraphs (4) to (6), decrease the maximum price of a presentation by direction to a specific manufacturer or supplier.

(2) Unless the number of applications received by the Secretary of State makes it impracticable to do so, the Secretary of State must within 90 days of receiving all of the information received as part of an application made under paragraphs (4) to (6), specify the maximum price at which that presentation may be supplied to a manufacturer or supplier.

(3) 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 the 90 day period, the Secretary of State must notify the specific manufacturer or supplier within the 90 day period, and may extend that period for a further 60 days.

(4) A request 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 request is made;
- (b) state the reasons for the request; and
- (c) specify the proposed reduced maximum price.

(5) Where further information is required, the Secretary of State must within 28 days of receiving the information under paragraph (4) notify, and where appropriate, by giving an information notice, the manufacturer or supplier that further information is required.

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(6) Information provided to the Secretary of State under this regulation must be accompanied by a written declaration of approval.

Former voluntary scheme members

13.—(1) Where these Regulations apply to a manufacturer or supplier after they have left a voluntary scheme the maximum price will be the price in the [name of list] as referred to in regulation 8 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 relevant voluntary scheme;
- (b) any permanent increases of price under that scheme; and
- (c) any other reasonable factors.

Enforcement of recoverable sum

14.—(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 4 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

15.—(1) Where any amount of the recoverable sum notified to the manufacturer or supplier is not paid in accordance with a notice under regulation 14, 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 as it may be 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

16.—(1) A manufacturer or supplier who contravenes regulation 9(1) must, on the demand of the Secretary of State, pay to the Secretary of State a single penalty not exceeding £100,000.

(2) The penalty referred to in paragraph (1) may be determined by the Secretary of State, having regard to, among other relevant factors, the following factors—

- (a) whether the manufacturer or supplier has previously contravened regulation 9(1);

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- (b) the net sales income of the manufacturer or supplier;
 - (c) the estimated quantity of supply of the presentation; and
 - (d) the difference between the gross sales income that the manufacturer or supplier received for the supply of the presentation prior to the determination of the maximum price by the Secretary of State and the maximum price as determined by the Secretary of State.
- (3) A manufacturer or supplier who contravenes regulation 8 must, on the demand of the Secretary of State, pay to the Secretary of State a daily penalty calculated under Schedule 5.
- (4) A demand made under paragraph (1) or (3) 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.
- (5) For the purposes of paragraph (4), the Secretary of State may request information from the manufacturer or supplier.

**PART 3
INFORMATION REQUIREMENTS**

Provision of information for payment scheme

- 17.**—(1) Subject to regulation 18, a manufacturer or supplier required to make payments under regulation 3, must provide to the Secretary of State information in accordance with Schedule 1.
- (2) The Secretary of State may require a manufacturer or supplier required to make payments under regulation 4 to provide to the Secretary of State information in accordance with Schedule 1.

New manufacturer or supplier

- 18.**—(1) A new manufacturer or supplier required to make payments under regulation 3 must provide to the Secretary of State information in accordance with Schedule 3.
- (2) The Secretary of State may require a manufacturer or supplier required to make payments under regulation 4 to provide to the Secretary of State information in accordance with Schedule 3.
- (3) Where a new manufacturer or supplier has provided sales reports in accordance with paragraph 7 of Schedule 3, the Secretary of State may request an audited sales report to be provided within a period of not less than 3 months where the Secretary of State reasonably considers that this is required to verify the information that has been provided.
- (4) A request under paragraph (3) must not require information to be provided before the first 9 months following the last day of the manufacturer's or supplier's Financial Year.
- (5) If on review of the audited sales reports the Secretary of State reasonably believes that a new manufacturer or supplier had sales of presentations in its first Financial Year of either less or more than the thresholds set out at paragraph 2 of Schedule 3, then regulation 24 will apply.

Small manufacturer or supplier

- 19.**—(1) A manufacturer or supplier that would be required to make payments under regulation 3 or 4 were it not for the fact that they are a small manufacturer or supplier must provide to the Secretary of State details of their total net sales income in accordance with Schedule 2.

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(2) Where a small manufacturer or supplier has provided information under paragraph (1), the Secretary of State may, in accordance with paragraphs (3) to (5), also request audited information to be provided in relation to their total net sales income.

(3) The Secretary of State may request audited information to be provided where the Secretary of State reasonably considers that this is required to verify the information that has been provided.

(4) A request made under paragraph (2) may require the audited information to be provided within a period of not less than 3 months of the request.

(5) A request made under paragraph (2) must not require information to be provided before the first 9 months following the last day of the manufacturer's or supplier's Financial Year.

(6) If on review of the audited sales reports the Secretary of State reasonably believes that a small manufacturer or supplier had sales of presentations in its first Financial Year of either less or more than the thresholds set out for small manufacturers or suppliers in the table in Schedule 2, then regulation 24 will apply.

Sales report

20.—(1) Where a manufacturer or supplier is required to provide the Secretary of State with a “sales report” by these Regulations, the sales report must set out—

- (a) the total of the net sales income of the manufacturer or supplier;
- (b) the total of the net sales income received in respect of the total supply of all presentations excluding—
 - (i) the supply of any item of presentation which was procured under one or more framework agreement under the Public Contracts Regulations 2006^(a), the Public Contracts (Scotland) Regulations 2012^(b), the Public Contracts Regulations 2015^(c) or the Public Contracts (Scotland) Regulations 2015^(d)—
 - (aa) 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
 - (bb) until the day after the day at the end of which the relevant framework agreement expires; and
 - (ii) any low cost presentations;
- (c) the total payments required from the manufacturer or supplier in accordance with regulations 3 or 4;
- (d) details of the framework agreements from which the presentations in sub-paragraph (b)(i) were procured;
- (e) the total of the net sales income received in respect of the total supply of all of the presentations in sub-paragraph (d);
- (f) the low cost presentations supplied and the total of the net sales income received in respect of the total supply of all of those presentations;
- (g) the products other than medicinal products supplied and the total of the net sales income received in respect of the total supply of all of those products;
- (h) the medicinal products supplied to outside of the UK and the total of the net sales income received in respect of the total supply of all of those products;

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

(b) SSI 2015/88.

(c) S.I 2015/102 to which there are amendments not relevant to these Regulations.

(d) SSI 2015/446.

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- (i) the medicinal products supplied for purposes other than for health service use and the total of the net sales income received in respect of the total supply of all of those medicinal products; and
 - (j) the unbranded generic health service medicines supplied and the total of the net sales income received in respect of the total supply of all of those unbranded generic health service medicines.
- (2) Paragraph (3) applies where it is not possible to distinguish, in information relating to net sales income, between—
- (a) medicinal products that are or were for health service use; and
 - (b) medicinal products that are or were not for health service use.
- (3) Where this paragraph applies, a manufacturer or supplier must provide information on the basis of a best estimate of the net sales income for medicinal products that are or were likely to be for health service use, but only if, when it provides the information to the Secretary of State, the producer explains to the satisfaction of the Secretary of State—
- (a) the method of calculating the best estimate; and
 - (b) why the information could only be provided on the basis of a best estimate of the net sales income for medicinal products that are likely to be for health service use.

Presentation report

21.—(1) Where a manufacturer or supplier is required to provide the Secretary of State with a “presentation report” by these Regulations, the presentation report must, with respect to each presentation, separately set out —

- (a) the name of each presentation;
 - (b) except in relation to the supply of excluded presentations specified in paragraph (2), the quantity of each presentation supplied to—
 - (i) wholesalers;
 - (ii) primary medical services providers;
 - (iii) NHS chemists;
 - (iv) relevant UK hospitals; or
 - (v) any other persons or bodies supplied by it with presentations for health service use;
 - (c) except in relation to the supply of excluded presentations specified in paragraph (2), the total gross sales income and total net sales income received for the supply of each presentation to each of the categories listed in sub-paragraph (b);
 - (d) the quantity supplied and the total gross sales income and total net sales income received for the supply of each presentation which was procured under one or more framework agreements under the Public Contract Regulations 2006, the Public Contracts (Scotland) Regulations 2012, the Public Contracts Regulations 2015 or the Public Contracts (Scotland) Regulations 2015—
 - (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;
 - (e) the quantity supplied and the total gross sales income and the total net sales income received for the supply of each low cost presentation.
- (2) For the purposes of paragraphs (1)(b) and (1)(c), the supply of excluded presentations is—

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- (a) the supply of presentations procured under one or more framework agreements under the Public Contracts Regulations 2006, the Public Contracts (Scotland) Regulations 2012, the Public Contracts Regulations 2015 or the Public Contracts (Scotland) Regulations 2015—
 - (i) where the framework agreement was entered into on or before [the date of coming into force of the Regulations] or was entered into 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;
- (b) the supply of low cost presentations.

Audited information

22.—(1) Any information required to be audited by these Regulations, including audited sales report, must be prepared and approved by the manufacturer or supplier and audited by a qualified independent auditor and must be accompanied with—

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

(2) 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

23.—(1) Where a manufacturer or supplier is required to provide any information by these Regulations 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 by 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 gives a true and fair account of the information required and must include a statement to that effect in the written declaration of approval.

Review

24.—(1) If, on review of estimated information or audited information, and in accordance with paragraph (2), the Secretary of State reasonably believes that a manufacturer or supplier has paid an amount different to the amount required by regulations 3 or 4 the Secretary of State may either

(a) Registered Number 02486368.

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on the Secretary of State's 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
- (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 3 or 4 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;
- (d) the manufacturer's or supplier's appeal rights.

(4) The Secretary of State may request additional information from the manufacturer or supplier, either as part of or further to a review carried out under this regulation, including an updated sales report to reflect changes in the amounts paid or to be paid.

Penalties

25.—(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, and where appropriate by giving an information notice, 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 17, 18, 19, 20, 21, 22, 23 or 24, 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 5 to these Regulations.

(4) Where a manufacturer or supplier has failed to make a payment under regulation 3 or 4, and failed to provide information under this Part for the same quarter, quarters or remaining period, the Secretary of State may make a demand for a penalty under regulation 7 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) the manufacturer or supplier's appeal rights.

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PART 4

GENERAL PROVISIONS

Appeals

26.—(1) Any manufacturer or supplier in respect of whom the Secretary of State has made an enforcement decision under these Regulations has a right of appeal against that decision in accordance with the Health Service Medicines (Price Control Appeal) Regulations(a).

(2) In this regulation an enforcement decision includes any decision relating to information that is required by virtue of an information notice under section 264A(5) of the 2006 Act.

Revocation

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

Annual review

28.—(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) Under this regulation, “review period” means the period of one year beginning on [coming into force date].

Signed by authority of the Secretary of State for Health

Name

Date

Department of Health

(a) S.I. 2000/124 as amended by S.I. 2000/870 and 2007/1898.
(b) S.I. 2007/1320 as amended by S.I. 2008/1938 and 3258, 2013/325 and 2881 and 2015/233.
(c) S.I. 2008/3258 as amended by S.I. 2012/1916, 2013/2881 and 2015/233.

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SCHEDULES

SCHEDULE 1

Regulations 3, 4 and 17

GENERAL PROVISIONS FOR PAYMENT SCHEME

Payment scheme requirements

1. Payments required by regulation 3 or 4 must—

(1) be paid in accordance with table 1 so that they are made in respect of the period specified in Column (1) within the period specified in column (2);

(2) be paid by electronic transfer no later than the last day of the period within which payment must be made; and

(3) be calculated, where relevant, in accordance with the rules in paragraphs 3 to 9.

Table 1

<i>Column (1) Period to cover</i>	<i>Column (2) Period within which payment must be made</i>
Each quarter	Within 30 days of the last day of each quarter
Each remaining period	Within 30 days of the last day of each remaining period

Information requirements

2. Information required by regulation 17 must be—

(1) provided in accordance with table 2 so that for the period specified in column (1), the information specified in column (2) must be provided within the period specified in column (3); and

(2) provided, where relevant, in accordance with the rules in paragraphs 3 to 9.

Table 2

<i>Column (1) Period to cover</i>	<i>Column (2) Information required</i>	<i>Column (3) Period within which information must be supplied</i>
Each quarter	Sales report	Within 30 days of the last day of each quarter
Each remaining period	Sales report	Within 30 days of the last day of each remaining period

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Each Financial Year	Presentation report	Within 2 months of the last day of the Financial Year
	Audited sales report	Within 9 months of the last day of the Financial Year
	Statutory audited accounts	Within 9 months of the last day of the Financial Year

Rules

3. The end date of the final period in the manufacturer's or supplier's Financial Year, be that the final quarter or remaining period, must be treated as extended or reduced by not more than seven days before or after that 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.

4. Where the payment percentage set out in regulation 3 or 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 3 or 4 begins to apply until the end of the relevant quarter or remaining period.

5. Where the payment percentage set out in regulation 3 or 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 stops applying.

6. 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 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.

7. 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.

8. 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 30 days.

9. A manufacturer's or supplier's "*previous Accounting Reference Period*" means the one immediately preceding its current Accounting Reference Period.

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SCHEDULE 2

Regulation 19

SMALL MANUFACTURER OR SUPPLIER

Payment scheme requirements

1. A small manufacturer or supplier means a manufacturer or supplier that has received in respect of the total supply of all presentations, a total of net 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 previous Accounting Reference Period specified in column (1) of the table.

Table

<i>Column (1) Length of Previous Accounting Reference Period</i>	<i>Column (2) Net sales income</i>
Twelve months	£5million
Less than twelve months	£5million as proportionately reduced to the number of months in the manufacturer's or supplier's Accounting Reference Period
More than twelve months	£5million in the final twelve months of the manufacturer's or supplier's Financial Year

Information requirements

2. A small manufacturer or supplier must in accordance with paragraphs 3 provide to the Secretary of State the total of the net sales income it received in respect of the total supply of all presentations.

3. The information supplied under paragraph 2 must—

- (a) be supplied for the complete Financial Year immediately preceding 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 complete Financial Year immediately preceding 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.

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5. The end date of the final period in the manufacturer's or supplier's Financial Year, be that the final quarter or remaining period, must be treated as extended or reduced by not more than seven days before or after that 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.

6. 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.

7. 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.

8. 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 30 days.

9. A manufacturer's or supplier's "*previous Accounting Reference Period*" means the one immediately preceding its current Accounting Reference Period.

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SCHEDULE 3

Regulation 3 and 18

**NEW MANUFACTURER OR SUPPLIER
PAYMENT SCHEME**

Payment requirements

1. Payments required by regulation 3 or 4 must—

(1) be paid in accordance with table 1 so that where the length of the period in Column (1) applies, the manufacturer or supplier will make payments in respect of each quarter or remaining period specified in Column (2) within the corresponding time in Column (3);

(2) be paid by electronic transfer; and

(3) be calculated, where relevant, in accordance with the rules in paragraphs 9 to 15.

2. The requirement to make payments under regulation 3 or 4 does not apply to—

(1) a new manufacturer or supplier if their estimate of the total of the net sales income likely to be received in respect of total supply of all presentations 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 net sales income in respect of relevant medicines.

Table 1

<i>Column (1) Length of current Accounting Reference Period</i>	<i>Column (2) Period to cover</i>	<i>Column (3) Period within which payment must be made</i>
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	Paragraph 3 applies	Paragraph 3 applies

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 a total of the net sales income in respect of the total supply of all presentations of £5 million or more, continue to make payments for any period

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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.

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 a total of net sales income in respect of total supply of all presentations 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 total of net sales income it is likely to receive in respect of the total supply of its presentations for its first Financial Year within 30 days of the date on which these Regulations come into force or, if the Regulations start to apply to the 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.

6. Where the estimate of the net sales income referred to in paragraph 5 is £5 million or more, the new manufacturer or supplier must in accordance with the rules in paragraphs 9 to 16, provide to the Secretary of State the information in column (2) of table 2 in respect of each corresponding quarter, remaining period or Financial Year specified in column (1) of that table no later than within the corresponding time in column (3) of that table.

Table 2

<i>Column (1) Period to cover</i>	<i>Column (2) Information to be provided</i>	<i>Column (3) Period within which information must be supplied</i>
Each quarter	Sales report	Within 30 days of the last day of that quarter
Each Remaining period	Sales report	Within 30 days of the last day of the remaining period
Financial Year	Presentation report	Within 2 months of the last day of the Financial Year.
	Audited Sales report	Within 9 months of the last day of the Financial Year.
	Statutory audited accounts	Within 9 months of the last day of the Financial Year

7. Where the estimate of the net sales income 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

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

Table 3

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

Rules

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

9. The end date of the final period in a manufacturer's or supplier's Financial Year, be that the final quarter or remaining period, must be treated as extended or reduced by not more than seven days before or after that 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 3 or 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 3 or 4 begins to apply until the end of the relevant quarter or remaining period.

11. Where the payment percentage set out in regulation 3 or 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.

12. 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.

13. 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 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.

14. 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 30 days.

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15. A manufacturer's or supplier's "*previous Accounting Reference Period*" means the one immediately preceding its current Accounting Reference Period.

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SCHEDULE 4

Regulations 6 and 15

RECOVERABLE SUMS

1. For the purposes of regulation 5, 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 5 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 the table.
2. For the purposes of regulation 15, 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 the table.
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

<i>Column (1)</i> <i>Contravention</i>	<i>Column (2)</i> <i>Additional Percentage</i>
First contravention	5 per cent
Second contravention	15 per cent
Third contravention	25 per cent
Fourth contravention	35 per cent
Fifth or subsequent contravention	50 per cent

4. For the purposes of this Schedule—
 - (a) “second contravention” means in relation to paragraph 1 of this Schedule, a contravention of regulation 3 or 4 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 3 or 4, and in relation to paragraph 2 of this Schedule where the same presentation continues to be supplied for a further period of one month from the date of a previous contravention which relates to that product.

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SCHEDULE 5

Regulations 7, 16 and 25

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 net sales income for total supply of all presentations 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

<i>Column (1)</i>	<i>Column (2)</i>	<i>Column (3)</i>
<i>Total net sales income in most recent complete Financial Year or if a new manufacturer or supplier, total estimate of net sales income of relevant medicines for first 12 months of Accounting Reference Period since date of incorporation</i>	<i>Daily penalty for first 14 days</i>	<i>Daily penalty for subsequent days</i>
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 net 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

<i>Column (1)</i>	<i>Column (2)</i>	<i>Column (3)</i>
<i>Total United Kingdom sales</i>	<i>Daily penalty for first 14 days</i>	<i>Daily penalty for subsequent days</i>
Less than £100 million	£2,500	£5,000
£100 million or more	£5,000	£10,000

3. Subject to paragraph 4, for the purposes of table 2, the total United Kingdom sales will be calculated at the time the penalty becomes payable by reference to its total sales in the United Kingdom as shown in its statutory audited accounts or where the manufacturer or supplier does not have statutory audited accounts, its statutory accounts, for its most recent complete Financial Year.

4. For the purposes of table 2, the total United Kingdom sales of a new manufacturer or supplier will be assumed to be less than £100 million.