STATUTORY INSTRUMENTS

2018 No. 345

The Branded Health Service Medicines (Costs) Regulations 2018

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Branded Health Service Medicines (Costs) Regulations 2018 and come into force on 1st April 2018.

(2) In these Regulations—

"the 1978 Act" means the National Health Service (Scotland) Act 1978(**1**);

"the 2006 Act" means the National Health Service Act 2006;

"the 2006 Wales Act" means the National Health Service (Wales) Act 2006(**2**);

"the 2008 Regulations" means the Health Service Branded Medicines (Control of Prices and Supply of Information)(No.2) Regulations 2008(**3**);

"the 2012 Regulations" means the Human Medicines Regulations 2012(**4**);

"accounting reference date" has the meaning given to it under section 391 of the Companies Act 2006(**5**);

"accounting reference period" has the meaning given to it under section 391 of the Companies Act 2006;

"audited sales report" means a sales report audited in accordance with regulation 23(1);

"branded medicine" means a medicinal product to which a brand name has been applied that enables the medicine to be identified without reference to the common name;

"common name" in respect of a medicinal product means the non-proprietary name or if one does not exist, the usual common name;

"contracting authority" in relation to a contract based on a framework agreement has the meaning given to it by regulation 3 of the Public Contracts Regulations 2006(**6**), regulation 3 of the Public Contracts (Scotland) Regulations 2012(**7**), regulation 2 of the Public Contracts Regulations 2015(**8**) or regulation 2 of the Public Contracts (Scotland) Regulations 2015(**9**) under which the relevant framework agreement was concluded;

"duration of supplementary certificate" is to be construed in accordance with article 13 of Regulation (EC) 469/2009 of the European Parliament and of the Council of 6th May 2009 concerning the supplementary protection certificate for medicinal products(**10**);

(**1**) 1978 c. 29.
(**2**) 2006 c. 42.
(**3**) S.I. 2008/3258 amended by S.I. 2012/1916, 2013/2881 and 2015/233, revoked with a saving provision by the coming into force of regulation 28 of these Regulations.
(**4**) S.I. 2012/1916 to which there are amendments not relevant to these Regulations.
(**5**) 2006 c. 46.
(**6**) S.I. 2006/5 revoked by regulation 116 of the Public Contracts Regulations 2015 (S.I. 2015/102).
(**7**) S.S.I. 2012/88 revoked by regulation 97 of the Public Contracts (Scotland) Regulations 2015 (S.S.I. 2015/446).
(**8**) S.I. 2015/102 to which there are amendments not relevant to this definition.
(**9**) S.S.I. 2015/446 to which there are amendments not relevant to these Regulations.
(**10**) OJ No L 152, 16.06.2009, p1 amended by the Treaty of Accession of Croatia (OJ No L 112, 24.4.2012, p10).

"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;

"framework agreement" has the meaning given to it by regulation 2 of the Public Contracts Regulations 2006, regulation 2 of the Public Contracts (Scotland) Regulations 2012, regulation 33(2) of the Public Contracts Regulations 2015 or regulation 2 of the Public Contracts (Scotland) Regulations 2015 under which the framework agreement was concluded;

"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;

"group" has the meaning given to it under section 474(1) of the Companies Act 2006;

"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 Health and Social Care (Reform) Act (Northern Ireland) 2009(**11**);

(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;

"individual accounts" means accounts of the manufacturer or supplier prepared in accordance with section 394 of the Companies Act 2006;

"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, for each item of presentation of less than £2.00;

"marketing authorisation" has the meaning given by regulation 8(1) of the 2012 Regulations;

"marketing authorisation holder" means a manufacturer or supplier that holds a marketing authorisation;

"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 BSA" means the NHS Business Services Authority established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005(**12**);

"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(**13**); 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);

(b) an International Non-proprietary Name Modified (INNM);

(**11**) 2009 c. 1 (N.I.).
(**12**) S.I. 2005/2414.
(**13**) *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.

(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(**14**) which has been prepared and published under regulation 318 of the 2012 Regulations (list of names) and which is in force;

"parallel distributed presentation" means a presentation in respect of which a parallel distribution notice(**15**) with the United Kingdom as the Member State of destination has been given;

"patent protection period" means the total period of the term of patent and if a supplementary protection certificate has been granted, the duration of the supplementary protection certificate;

"prescription only medicine" is to be construed in accordance with regulation 5 of the 2012 Regulations;

"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, method of administration or formulation;

"presentation report" is to be construed in accordance with the requirements of regulation 22;

"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(**16**), a contract under section 17J of the 1978 Act(**17**) or an agreement under section 17C of the 1978 Act(**18**); or

(d) Part 2 or 6 of the Health and Personal Social Services (Northern Ireland) Order 1972(**19**);

"public contract" has the meaning given to it by regulation 2 of the Public Contracts Regulations 2006, regulation 2 of the Public Contracts (Scotland) Regulations 2012, regulation 2 of the Public Contracts Regulations 2015(**20**) or regulation 2 of the Public Contracts (Scotland) Regulations 2015 under which the relevant contract was awarded;

"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 even if there are more than four such periods in that financial year;

"relevant medicine" means a health service medicine—

(a) which is a branded medicine;

(**14**) Copies can be obtained from https://www.pharmacopoeia.com/what-is-the-ban-book or the Stationery Office, PO Box 29, Norwich, NR3 1GN.

(**15**) *See* Article 57(1)(o) of Regulation (EC) 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 (OJ No L 136, 30.04.2004, p1) as last amended by Regulation No 1072/2012 of the European Parliament and of the Council of 25 October 2012 (OJ No L316 14.11.2012, p38).

(**16**) 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.

(**17**) Section 17J was inserted by the Primary Medical Services (Scotland) Act 2004 (asp 1), section 4.

(**18**) 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 (asp 1), section 2(2); and the Health and Social Care Act 2012 (c. 7), Schedule 21, paragraph 3(2)(a).

(**19**) S.I. 1972/1265 (N.I. 14).

(**20**) S.I. 2015/102, amended by S.I.2016/275; there are other amending instruments but none is relevant.

(b) which is a medicine 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(**21**),

(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(**22**) as being drugs, medicines or other substances which may not be ordered by a 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(**23**) 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(**24**), 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(**25**);

"relevant NHS BSA online gateway" means the service provided for on the NHS BSA website for receiving information for the purpose in question(**26**);

"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(**27**);

(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" is to be construed in accordance with the requirements of regulation 21(1);

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

"statutory audited accounts" means—

(a) in relation to individual accounts of the manufacturer or supplier required to be audited in accordance with Part 16 of the Companies Act 2006, the individual accounts audited in accordance with Part 16 of that Act;

(b) in relation to individual accounts of the manufacturer or supplier exempt from audit under Part 16 of the Companies Act 2006 in accordance with section 477 of that Act, the individual accounts of the manufacturer or supplier;

(**21**) S.I. 2004/629.
(**22**) 1978 c. 29; section 17N was inserted by section 4 of the Primary Medical Services (Scotland) Act 2004 (asp 1).
(**23**) 1978 c. 29; section 17J was inserted by section 4 of the Primary Medical Services (Scotland) Act 2004 (asp 1).
(**24**) S.R. (NI) 2004 No. 142.
(**25**) S.I. 2004/1022.
(**26**) The website address is https://apps.nhsbsa.nhs.uk/infosystems/welcome.
(**27**) Sections 390, 391 and 392 of the Companies Act 2006 (c. 46) 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.

(c) in relation to individual accounts of the manufacturer or supplier exempt from audit under Part 16 of the Companies Act 2006 in accordance with section 479A of that Act, the consolidated accounts of the parent undertaking in the same group as the manufacturer or supplier as referred to in subsection (2)(c) of that section;

"supplementary protection certificate" means a certificate granted in accordance with Regulation (EC) 469/2009 of the European Parliament and of the Council of 6th May 2009 concerning the supplementary protection certificate for medicinal products;

"supply" means supply by way of sale unless the context otherwise requires;

"term of patent" is to be construed in accordance with section 25 of the Patents Act 1977(**28**);

"unbranded generic health service medicine" means a health service medicine the labelling of which includes the common name of the medicinal product but does not include an invented name;

"UK health service hospital" means a body which —

(a) is mentioned in Part 3 of Schedule 1 to the Freedom of Information Act 2000(**29**) 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

(b) is mentioned in Part 4 of Schedule 1 to the Freedom of Information (Scotland) Act 2002(**30**) 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(**31**);

"voluntary scheme presentation" means a presentation covered by a voluntary scheme at the time of supply of that presentation;

"wholesale dealer's licence" is to be construed in accordance with regulation 18 (wholesale dealing in medicinal products) of the 2012 Regulations; and

"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.

(3) Where, under these Regulations, something is to be done within a specified number of—

(a) days of an occurrence, that number of days includes the day of the occurrence; or

(b) months of an occurrence, the first month starts on and includes the day of the occurrence (so a three month period starting on the 1st January ends on 31st March).

(4) Where, under these Regulations, the amount of interest on, or a penalty for, an unpaid amount that is overdue is calculated by reference to a number of days—

(a) the day on which payment in full is received does not count towards the calculation of that number of days; and

(b) in the event of part payment, interest on the outstanding amount is to be recalculated from the start of the day of the part payment.

(5) Where under these Regulations, information in any form is required to be provided via a relevant NHS BSA online gateway, unless the contrary is proved—

(**28**) 1977 c. 37; section 25(3) was amended subject to transitional provisions specified in article 3 of S.I. 2005/2471 of the Patents Act 2004 (c.16), section 8(1). Section 25(4) was amended by the Patents Act 2004 (c.16), section 8(2).
(**29**) 2000 c. 36.
(**30**) 2002 asp 13.
(**31**) 2006 c. 41; section 261(1) was amended by the Health Service Medical Supplies (Costs) Act 2017 (c.23), section 3(2)(a).

(a) the use of that online gateway is presumed to have resulted in the information being successfully provided only if the information has been successfully recorded by the NHS BSA;

(b) the time of providing that information is presumed to be the time recorded by the NHS BSA as being the time it was provided;

(c) the person providing the information is presumed to be the person identified as such in any information recorded by the NHS BSA; and

(d) a return made on behalf of a body corporate is presumed to be a return made with the authority of that body corporate.

Application

2. These Regulations do not apply to any manufacturer or supplier to whom a voluntary scheme applies (all of whose relevant medicines are covered by that scheme).

PART 1

PAYMENT SCHEME

Payment scheme

3.—(1) Subject to paragraph (4), the manufacturer or supplier that is responsible for the first relevant supply of an item of presentation must pay 7.80% of the net sales income received in respect of that supply to the Secretary of State in accordance with Schedule 1.

(2) Subject to paragraph (3), for these purposes the first relevant supply is the first occasion on which that item of presentation is supplied by any manufacturer or supplier having a place of business in the United Kingdom (MS1) to another person having a place of business in the United Kingdom (MS2) that is not in the same group as MS1.

(3) If MS2 is—

(a) the marketing authorisation holder (MAH) in respect of that item of presentation; or

(b) a manufacturer or supplier in the same group as MAH,

the first relevant supply is the next supply of that item of presentation to a person having a place of business in the United Kingdom that is not in the same group as MS2.

(4) Subject to paragraph (5), paragraph (1) does not apply to the net sales income received in respect of the supply of—

(a) any item of presentation which was in respect of that supply, supplied under—

(i) a contract with a contracting authority based on a framework agreement where that framework agreement was entered into on or 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,

(ii) a public contract entered into on or 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) any item of low cost presentation;

(c) any item of parallel distributed presentation;

(d) any item of voluntary scheme presentation.

(5) Paragraph (4)(a) does not apply to any item of presentation added to a framework agreement or public contract after the coming into force of these Regulations.

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

Direction to make a payment

4.—(1) This regulation applies where the Secretary of State considers that a manufacturer or supplier has entered into an arrangement whose main purpose or one of whose main purposes is to reduce or avoid a payment in respect of a sale of any item of presentation that either that or another manufacturer or supplier would otherwise be liable to make under regulation 3.

(2) Where this regulation applies the Secretary of State may give a direction to any manufacturer or supplier that has entered into such an arrangement to do either or both of the following—

(a) pay the amount so reduced or avoided in relation to such a sale;

(b) pay 7.80% in respect of any future sale of any item of that presentation under that arrangement in accordance with Schedule 1.

(3) Any direction given under paragraph (2) must specify—

(a) the reason why the Secretary of State considers that the manufacturer or supplier should pay the amount;

(b) the reduced or avoided amount of payment that the manufacturer or supplier must pay to the Secretary of State in relation to the sale referred to in paragraph (2)(a) and the period within which it must be paid;

(c) whether the manufacturer or supplier is required to pay 7.80% in respect of the sale referred to in paragraph (2)(b); and

(d) the manufacturer's or supplier's appeal rights.

(4) In this regulation—

"an arrangement" includes any scheme, arrangement or understanding, whether or not legally enforceable;

"supplier" means any person who supplied any item of presentation and is not limited to circumstances where that supply is by way of sale.

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

Interest payable on late payment

5.—(1) Paragraph (2) applies where—

(a) the whole or any part of the amount required to be paid by a manufacturer or supplier under regulation 3 is not paid in accordance with table 1 of Schedule 1 and so an amount is overdue; or

(b) the whole or any part of the amount required to be paid by a manufacturer or supplier under a direction given under regulation 4 is not paid in accordance with that direction, and so an amount is overdue.

(2) Where this paragraph applies, the manufacturer or supplier is liable to pay to the Secretary of State interest, calculated in accordance with paragraph (3) read with regulation 1(4) and 7(4), on the amount referred to in paragraph (1)(a) or (b) which is overdue until that amount is paid.

(3) The interest payable under paragraph (2) shall be simple interest calculated from day to day 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 and applied to any amount outstanding on that day.

(4) 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(**32**) (reserve powers) is in force, any equivalent rate determined by the Treasury under that section.

Penalties

6.—(1) Paragraph (2) applies where—

(a) the whole or any part of the amount required to be paid by a manufacturer or supplier under regulation 3 is not paid in accordance with table 1 of Schedule 1 and so an amount is overdue; or

(b) the whole or any part of the amount required to be paid by a manufacturer or supplier under a direction given under regulation 4 is not paid in accordance with that direction, and so an amount is overdue.

(2) Where this paragraph applies, the manufacturer or supplier is liable to pay to the Secretary of State a penalty, calculated on a daily basis in accordance with Schedule 5 read with regulations 1(4) and 7(4), until the overdue amount referred to in paragraph (1)(a) or (b) is paid.

Demands and appeals

7.—(1) Paragraph (2) applies where—

(a) the whole or any part of the amount required to be paid by a manufacturer or supplier under regulation 3 is not paid in accordance with table 1 of Schedule 1 and so an amount is overdue; or

(b) the whole or any part of the amount required to be paid by a manufacturer or supplier under a direction given under regulation 4 is not paid in accordance with that direction, and so an amount is overdue.

(2) Where this paragraph applies the Secretary of State may make a demand for payment from the manufacturer or supplier in respect of the overdue amount.

(3) A demand made under paragraph (2) must be issued by way of a written notice to that manufacturer or supplier and must state—

(a) the overdue amount referred to in paragraph (1)(a) or (b);

(b) the amount of interest calculated in accordance with regulation 5(3) up to the date on which the demand is made;

(c) the amount of penalty calculated in accordance with regulation 6(2) up to the date on which the demand is made;

(d) the daily rate at which the interest and penalty continues to accrue for as long as the amount referred to in paragraph (1)(a) or (b) continues to be overdue; and

(e) the manufacturer's or supplier's appeal rights.

(4) If a manufacturer or supplier sends a notice of an appeal to the Tribunal in accordance with regulation 4 of the Health Service Medicines (Price Control Appeal) Regulations 2000(**33**), in respect of a demand issued by way of a written notice under paragraph (3), the period beginning on the date that the notice is received by the Tribunal to the date on which the appeal is finally determined or

(**32**) 1998 c. 11.
(**33**) S.I. 2000/124 as amended by S.I. 2000/870 and 2007/1898.

is withdrawn is discounted for the purposes of the calculation of the number of days in respect of which an amount referred to in paragraph (1)(a) or (b) is overdue.

PART 2

MAXIMUM PRICES

Maximum price

8.—(1) Subject to paragraphs (2) and (4), the maximum price which may be charged by a manufacturer or supplier for the supply of each item of a presentation is the maximum price set out in the most recent direction given under paragraph (3) or regulation 9(5), (7), 10(1), 11(2), 12(2) or 13(1) in respect of that presentation.

(2) Where, in respect of a presentation, there is no direction as referred to in paragraph (1), the maximum price which may be charged by a manufacturer or supplier for the supply of each item of a presentation is—

(a) where a presentation was on sale for health service use before 1st December 2013—

(i) the price, as determined by the Secretary of State, at which an item of that presentation was on sale for health service use without regard to any discount or variation of that price which did not have general application on that date, or

(ii) where the Secretary of State specified an increase in the price of an item of presentation in accordance with regulation 6 of the 2008 Regulations, the specified increased price;

(b) where the presentation was first made available for sale for health service use on or after 1st December 2013—

(i) the price, as specified by the Secretary of State in accordance with regulation 3 of the 2008 Regulations, or

(ii) where the Secretary of State specified an increase in the price of an item of presentation in accordance with regulation 6 of the 2008 Regulations, the specified increased price.

(3) Where the price of a presentation first made available for sale for health service use on or after 1stDecember 2013 was not specified by the Secretary of State as set out in paragraph (2)(b)(i), the Secretary of State may specify the maximum price which may be charged by a manufacturer or supplier for the supply of each item of that presentation by direction to a specific manufacturer or supplier.

(4) Subject to paragraph (5), with respect to the supply of any item of presentation supplied under a contract with a contracting authority based on a framework agreement or supplied under a public contract—

(a) paragraph (1) does not apply where the framework agreement or public contract was entered into before the date that the direction under paragraph (3) or regulation 9(5), (7), 10(1), 11(2), 12(2) or 13(1) was given, or was entered into following a tender which closed on or before that date;

(b) paragraph (2) does not apply where the framework agreement or public contract 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 that date.

(5) Paragraph (4) does not apply to any item of presentation added to a framework agreement or public contract after the date referred to in each corresponding sub-paragraph of paragraph (4).

New presentation

9.—(1) A manufacturer or supplier intending to place on the market a new presentation must record and keep for a period of 6 years information required under this regulation.

(2) At least 60 days prior to the proposed 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.

(3) A notification under paragraph (2) 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) include 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).

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

(5) Unless further information relating to the factors listed at paragraph (8) is requested, the Secretary of State must specify the maximum price at which that new presentation may be supplied by direction to the manufacturer or supplier within a period of 28 days of receiving the information under paragraph (4).

(6) Where further information relating to the factors listed at paragraph (8) 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, and inform the manufacturer or supplier of the maximum price within 28 days of receiving that further information.

(7) Where a manufacturer or supplier fails to notify the Secretary of State of its intention to place the presentation on the market within the 60 day period referred to in paragraph (2) 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, by direction, specify the maximum price of that presentation.

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

(a) the clinical need for the new presentation at the time that the notification under paragraph (2) is made and during the period that the notification is being considered by the Secretary of State;

(b) the price and associated operational costs of therapeutically equivalent or comparable medicines to that new presentation at the time that the notification under paragraph (2) is made and during the period that the notification is being considered by the Secretary of State;

(c) the price and associated operational costs of the new presentation in the European Economic Area and any other markets if it is available elsewhere in the world at the time that notification under paragraph (2) is made and during the period that the notification is being considered by the Secretary of State;

(d) whether the presentation contains a new active substance;

(e) the date on which the patent protection period for each indication of the new presentation expires;

(f) the total profit of the manufacturer or supplier before interest charges and taxes for their previous accounting reference period as set out in the manufacturer's or supplier's individual 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 period;

(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 period, 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(**34**) in relation to the presentation in accordance with Article 13.3 of the Regulation (EC) 726/2004 of the European Parliament and of the Council of 31st 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 confirms that the presentation contains a new active substance; or

(b) the Assessment Report published by the licensing authority in relation to the presentation in accordance with Article 21 of the Directive 2001/83/EC of the European Parliament and of the Council of 6th November 2001 on the Community code relating to medicinal products for human use(**35**) 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 (3) must be made, is not subject to a maximum price under regulation 8(2) or under a direction made under regulation 8(3), 10(1), 11(2), 12(2), or 13(1).

(12) In this regulation—

"licensing authority" is to be construed in accordance with regulation 6 of the 2012 Regulations; and

"summary of product characteristics" is to be construed in accordance with regulation 8(1) of the 2012 Regulations.

(**34**) As established under Regulation (EC) 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 (OJ No L 136, 30.04.2004, p 1).

(**35**) OJ No L 311, 28.11.2001, p.67; article 21 was amended by Directive 2011/62/EU of the European Parliament and of the Council of 15 December 2010 (OJ No. L 348 31.12.2010, p 74).

Temporary exemptions

10.—(1) The Secretary of State may by direction, exempt for such temporary period as the Secretary of State may determine a presentation from the effect of regulation 8(1) or (2) 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 given under paragraph (1)—

(a) the new temporary maximum price at which an item of presentation may be supplied for health service use; 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) A manufacturer or supplier intending to make an application for a price increase under this regulation must record and keep for a period of six years the information required for such an application under this regulation.

(2) Subject to paragraph (3), the Secretary of State must within a period of 90 days, following an application made under paragraphs (4) to (6), confirm or increase the maximum price of a presentation by direction to that manufacturer or supplier.

(3) Where the number of applications received by the Secretary of State under this regulation makes it impracticable for the Secretary of State to confirm or increase the maximum price, the Secretary of State may extend that period for a further 60 days and must notify the manufacturer or supplier if this is the case within the 90 day period.

(4) A request by a 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 paragraphs (7)(a) to (e), (f)(i), (f)(ii), (g)(i), (g)(ii) and (h).

(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 information required in relation to any of the relevant factors set out under paragraph (7)(f)(iii), (f)(iv), (g)(iii) and (g)(iv).

(6) Where further information relating to factors listed at paragraph (7) 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.

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

(a) the clinical need for the presentation at the time that the application under paragraph (4) is received by the Secretary of State and during the period that the application is being considered by the Secretary of State;

(b) the price and associated operational costs of therapeutically equivalent or comparable medicines to that presentation at the time that the application under paragraph (4) is received by the Secretary of State and during the period that the application is being considered by the Secretary of State;

(c) the price and associated operational costs of the presentation in the European Economic Area and any other markets if it is available elsewhere in the world at the time that the application under paragraph (4) is received by the Secretary of State and during the period that the application is being considered by the Secretary of State;

(d) the date on which the patent protection period for each indication of the presentation expires;

(e) the total profit of the manufacturer or supplier before interest charges and taxes for their previous accounting reference period as set out in the manufacturer's or supplier's individual accounts;

(f) 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 of items supplied and the total net sales income,

(ii) for the three financial years which follow the most recent one referred to in sub-paragraph (f)(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 first three financial years which follow the most recent one referred to in sub-paragraph (f)(iii), or where the patent protection period expires before the end of the three financial years, the period until the date of the expiration of the patent protection period from the first financial year following the most recent one referred to in subparagraph (f)(iii), including—

(aa) manufacturing and supply costs,

(bb) research and development costs,

(cc) operational costs, and

(dd) any other costs;

(g) 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, until the end of the latest complete month in the current financial year, the total quantity of items supplied and the total net sales income,

(ii) for the first three financial years which follow the most recent one referred to in sub-paragraph (g)(i), estimates of the total quantity of items 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 first three financial years which follow the most recent one referred to in sub-paragraph (g)(iii), or where the patent protection period of the presentation with respect to the presentation that the application is made under this regulation expires before the end of the three financial years, the period until the date of the expiration of the patent protection period from the first financial year following the most recent one referred to in paragraph (g)(iii), including—

(aa) manufacturing and supply costs,

(bb) research and development costs,

(cc) operational costs, and

(dd) any other costs;

(h) the price at which the manufacturer's or supplier's reasonable costs for the presentation, as determined by the Secretary of State would be met;

(i) 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, until the end of the latest complete month in the current financial year, and the following three financial years—

(i) if the presentation was supplied at its current maximum price, and

(ii) if the presentation was supplied at the proposed increase in maximum price.

(8) For the purposes of this regulation, where there is more than one patent protection period with respect to the presentation that the application under this regulation is made, the patent protection period which expires on the latest date will apply.

Decreases

12.—(1) A manufacturer or supplier intending to make an application for a price decrease under paragraph (4) must record and keep for a period of six years the information required for such an application under this regulation.

(2) Subject to paragraph (3), the Secretary of State must within a period of 28 days, on receipt of all of the information required as part of an application made by a manufacturer or supplier in accordance with paragraph (4), confirm or decrease the maximum price of a presentation by direction to that manufacturer or supplier.

(3) Where the number of applications received by the Secretary of State under this regulation makes it impracticable for the Secretary of State to reply to all or any of the applications within the 28 day period, the Secretary of State may extend that period for a further 28 days and must notify the manufacturer or supplier if this is the case within the 28 day period.

(4) A request by a manufacturer or supplier to the Secretary of State for a reduction of the maximum price of an item of 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.

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 which may be charged for an item of presentation by a manufacturer or supplier will be the price 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 relevant factors.

Recoverable sum

14.—(1) Paragraph (2) applies where a manufacturer or supplier supplies an item of presentation at a price in excess of the maximum price permitted by regulation 8.

(2) Where this paragraph applies, the manufacturer or supplier is liable to pay to the Secretary of State a recoverable sum, calculated in accordance with Schedule 4, until the maximum price that the manufacturer or supplier charges for an item of the presentation is the maximum price permitted by regulation 8.

Interest payable on late payment of the recoverable sum

15.—(1) Paragraph (2) applies where any amount of the recoverable sum notified to the manufacturer or supplier under regulation 17 is not paid in accordance with that notice and so is overdue.

(2) Where this paragraph applies, the manufacturer or supplier is liable to pay to the Secretary of State interest, calculated in accordance with paragraph (3) read with regulation 1(4) and 17(5), on the amount of the recoverable sum which is overdue until that sum is paid.

(3) The interest payable under paragraph (2) shall be simple interest calculated from day to day 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 applied to any amount outstanding on that day.

(4) 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) Paragraph (2) applies where a manufacturer or supplier supplies an item of presentation at a price in excess of the maximum price permitted by regulation 8.

(2) Where this paragraph applies, the manufacturer or supplier is liable to pay to the Secretary of State a penalty, calculated on a daily basis in accordance with Schedule 5 read with regulation 17(5) and (6), until the maximum price that the manufacturer or supplier charges for an item of that presentation is the maximum price permitted by regulation 8.

(3) Paragraph (4) applies where a manufacturer or supplier contravenes regulation 9(2).

(4) Where this paragraph applies, the manufacturer or supplier is liable to pay to the Secretary of State a single penalty not exceeding £100,000.

(5) The level of penalty referred to in paragraph (4) is to be determined by the Secretary of State, having regard to, among other factors, the following factors—

(a) whether the manufacturer or supplier has previously contravened regulation 8;

(b) the total 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.

Demands and appeals

17.—(1) Where a manufacturer or supplier is liable to pay a recoverable sum under regulation 14(2) the Secretary of State may make a demand for payment from the manufacturer or supplier.

(2) A demand made under paragraph (1) must be made by way of issuing a written notice to that manufacturer or supplier and must state—

(a) the amount of the recoverable sum calculated up to the date on which the demand is made;

(b) the date before the end of which the recoverable sum must be paid;

(c) the daily rate at which the interest, calculated in accordance with regulation 15(2) and payable once the recoverable sum is overdue, is to accrue for as long as the recoverable sum continues to be overdue; and

(d) the manufacturer's or supplier's appeal rights.

(3) Where a manufacturer or supplier is liable to pay a penalty under regulation 16(2) or (4), the Secretary of State may make a demand for payment of the penalty from the manufacturer or supplier.

(4) A demand made under paragraph (3) must be made by way of issuing a written notice to that manufacturer or supplier and must state—

(a) either or both of the following—

(i) the amount of penalty calculated in accordance with regulation 16(2) up to the date on which the demand is made,

(ii) the amount of penalty determined by the Secretary of State in accordance with regulation 16(5);

(b) the date before which the amounts referred to in sub-paragraphs (a)(i) or (ii) must be paid;

(c) with respect to a penalty calculated in accordance with regulation 16(2) the daily rate at which the penalty continues to accrue until the maximum price that that manufacturer or supplier charges for an item of the presentation is the maximum price permitted by regulation 8;

(d) the manufacturer's or supplier's appeal rights.

(5) If a manufacturer or supplier sends a notice of an appeal to the Tribunal in accordance with regulation 4 of the Health Service Medicines (Price Control Appeal) Regulations 2000, in respect of a demand issued by way of a notice under paragraph (2) or (4), the period beginning on the date that the notice is received by the Tribunal to the date on which the appeal is finally determined or is withdrawn is discounted for the purposes of the calculation of the number of days in respect of which—

(a) the recoverable sum is overdue; or

(b) the manufacturer or supplier supplies an item of presentation in excess of the maximum price permitted by regulation 8.

(6) For the purposes of calculating the amount of penalty by reference to a number of days, the day on which the manufacturer or supplier charges the maximum price permitted by regulation 8 for that presentation does not count towards the calculation of that number of days.

PART 3

INFORMATION REQUIREMENTS

Provision of information for payment scheme

18.—(1) A manufacturer or supplier required to make payments under regulation 3 or under a direction given under regulation 4(2)(b), must record and keep for a period of six years the information required under Schedule 1 and provide that information to the Secretary of State in accordance with Schedule 1.

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

New manufacturer or supplier

19.—(1) A new manufacturer or supplier required to make payments under regulation 3 or under a direction given under regulation 4(2)(b) must record and keep for a period of six years the information required under Schedule 3 and provide that information to the Secretary of State in accordance with Schedule 3.

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

Small manufacturer or supplier

20.—(1) A small manufacturer or supplier must record and keep the information required under Schedule 2 and provide that information to the Secretary of State in accordance with Schedule 2.

(2) Where a manufacturer or supplier has provided information in accordance with paragraphs 4 or 5 of Schedule 2, the Secretary of State may, for the purposes of verifying the information provided, request the manufacturer or supplier to provide that information in an audited form.

(3) A request under paragraph (2)—

(a) must be made within 12 months of receipt of the information provided in accordance with paragraphs 4 or 5 of Schedule 2;

(b) must require the audited sales report to be provided within a period of not less than 3 months and not more than 12 months of the date on which the Secretary of State made the request; and

(c) must not require the audited sales report to be provided before the completion of the first 9 months following the last day of the manufacturer's or supplier's financial year.

Sales report

21.—(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 be provided via the relevant NHS BSA online gateway and 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 for the total supply of all presentations in respect of which that manufacturer or supplier is required to make a payment under regulation 3 and any direction given under regulation 4;

(c) the total payments required from the manufacturer or supplier in accordance with regulation 3 and any direction given under regulation 4;

(d) with respect to a contract with a contracting authority based on a framework agreement under which the item of presentation supplied is excluded from the calculation of net sales income in accordance with regulation 3(4)(a)(i), details of the contract with the contracting authority, the framework agreement on which that contract is based and the item of presentation so supplied;

(e) with respect to a public contract under which the item of presentation supplied is excluded from the calculation of net sales income in accordance with regulation 3(4)(a)(ii), details of the public contract and the item of presentation so supplied;

(f) the total of the net sales income received in respect of the total supply of all of the items of presentations in sub-paragraphs (d) and (e);

(g) the items of low cost presentation supplied and the total of the net sales income received in respect of the total supply of all of those presentations;

(h) the items of parallel distribution presentation supplied and the total of the net sales income received in respect of the total supply of all of those presentations;

(i) the items of voluntary scheme presentation supplied and the total of the net sales income received in respect of the total supply of all of those presentations;

(j) information which verifies that the items of presentation in sub-paragraph (i) are items of voluntary scheme presentation;

(k) 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;

(l) the Non United Kingdom medicinal products supplied and the total of the net sales income received in respect of the total supply of all of those products;

(m) except the medicinal products listed at sub-paragraphs (o) and (p), 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;

(n) 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;

(o) the medicinal products subject to general sale supplied and the total of the net sales income received in respect of the total supply of all of those medicinal products; and

(p) the pharmacy medicines supplied and the total of the net sales income received in respect of the total supply of all of those pharmacy 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 medicinal products that are not or were not for health service use;

(b) medicinal products that are or were for use outside the United Kingdom and medicinal products that are not or were not for use outside of the United Kingdom.

(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, or that are or were for use outside of the United Kingdom, as the case may

be, 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 or that are likely to be for use outside of the United Kingdom, as the case may be.

(4) In this regulation—

"medicinal products subject to general sale" is to be construed in accordance with regulation 5 of the 2012 Regulations;

"Non United Kingdom medicinal products" means a medicinal product—

(a) which is a branded medicine;

(b) which is a prescription only medicine; and

(c) which is for use outside of the United Kingdom; and

"pharmacy medicines" is to be construed in accordance with regulation 5 of the 2012 Regulations.

Presentation report

22. Where a manufacturer or supplier is required to provide the Secretary of State with a "presentation report" by these Regulations, the presentation report must be provided via the relevant NHS BSA online gateway and, with respect to each presentation, separately set out—

(a) the name of each presentation supplied;

(b) except in relation to the supply of items of presentation specified in regulation 3(4), the quantity of each presentation supplied to—

(i) wholesalers,

(ii) primary medical services providers,

(iii) NHS chemists,

(iv) relevant UK hospitals, and

(v) any other persons or bodies;

(c) except in relation to the supply of items of presentations specified in regulation 3(4), the total gross sales income and total net sales income received for the supply of each presentation to each of the categories listed in paragraph (b);

(d) with respect to a contract with a contracting authority based on a framework agreement under which the item of presentation supplied is excluded from the calculation of net sales income in accordance with regulation 3(4)(a)(i), details of the contract with the contracting authority, the framework agreement on which that contract is based and the item of presentation so supplied;

(e) with respect to a public contract under which the item of presentation supplied is excluded from the calculation of net sales income in accordance with regulation 3(4)(a)(ii), details of the public contract and the item of presentation so supplied;

(f) the quantity supplied and the total gross sales income and total net sales income received for the supply of—

(i) each presentation which was supplied under a contract with a contracting authority based on a framework agreement, where the framework agreement was entered into on or before the date of coming into force of these Regulations or was entered into

following a tender which closed on or before the date of coming into force of these Regulations, and

(ii) each presentation which was supplied under a public contract 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;

(g) the quantity supplied and the total gross sales income and the total net sales income received for the supply of each low cost presentation;

(h) the quantity supplied and the total gross sales income and the total net sales income received for the supply of each parallel distributed presentation;

(i) the quantity supplied and the total gross sales income and the total net sales income received for the supply of each voluntary scheme presentation; and

(j) for the purposes of paragraph (i), information which verifies that the relevant presentation is a voluntary scheme presentation.

Audited information

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

(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(**36**); and

"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.

Written declaration of approval

24.—(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) in the case of 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

(**36**) Registered Number 02486368. Copies of the relevant statements and standards can be obtained from the Financial Reporting Council Limited, 8th Floor, 125 London Wall, London, EC2Y 5AS or at https://www.frc.org.uk/auditors/audit-assurance/standards-and-guidance.

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

25.—(1) If on a review of any information provided to the Secretary of State under these Regulations the Secretary of State considers that a manufacturer or supplier has paid an amount different to the amount required by regulation 3 or by a direction given under regulation 4, the Secretary of State may—

(a) by way of issuing a notice to the manufacturer or supplier require that person to pay an additional amount; or

(b) pay an amount to the manufacturer or supplier.

(2) The Secretary of State is to determine the amount referred to in paragraph (1) by determining the difference between the amount the manufacturer or supplier should have paid had the payment been made in accordance with regulation 3 or a direction given under regulation 4 and the amount actually received by the Secretary of State.

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

(4) A notice made under paragraph (1)(a) must be in writing and must specify—

(a) the period to which the amount to be paid relates;

(b) the amount to be paid referred to in paragraph (1);

(c) the period, which must not be less than 28 days from the date that the notice is issued by the Secretary of State, within which the payment must be made; and

(d) the manufacturer's or supplier's appeal rights.

(5) Where the Secretary of State considers that the information provided by a manufacturer or supplier under these Regulations does not reflect the information that is required to be kept and recorded by these Regulations, the Secretary of State may require that the manufacturer or supplier record and keep for a period of six years what the Secretary of State considers to be the correct information and provide that information or part of that information to the Secretary of State on request.

(6) In this regulation, "review of any information provided to the Secretary of State" includes review of estimated or audited information.

Penalties, demands and appeals

26.—(1) If the Secretary of State considers 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 complete 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) Paragraph (4) applies where a manufacturer or supplier contravenes regulation 18, 19, 20, 21, 22, 23, 24 or 25 or paragraph (1) of this regulation.

(4) Where this paragraph applies, the manufacturer or supplier is liable to pay to the Secretary of State a penalty, calculated on a daily basis in accordance with Schedule 5 read with paragraph (8) and (9), until the manufacturer or supplier complies with the relevant regulation (except to the extent that it is no longer possible to meet a deadline because the deadline has passed).

(5) Where a manufacturer or supplier is liable to pay a penalty, the Secretary of State may make a demand for payment from the manufacturer or supplier.

(6) A demand made under paragraph (5) must be made by way of issuing a written notice to that manufacturer or supplier and must state—

(a) the amount of the penalty calculated in accordance with paragraph (4) up to the date on which the demand is made;

(b) the date before which the penalty must be paid;

(c) the daily rate at which the penalty continues to accrue until the manufacturer or supplier complies with the relevant regulation (except to the extent that it is no longer possible to meet the deadline because the deadline has passed); and

(d) the manufacturer's or supplier's appeal rights.

(7) Where a manufacturer or supplier is liable to pay a penalty under regulation 6 and liable to pay a penalty under this regulation for failing to provide a sales report in respect of the same period in accordance with Schedule 1 or 3, as the case may be, the Secretary of State may make a demand for the payment of a penalty under regulation 7(3) or under paragraph (5) but not under both.

(8) If a manufacturer or supplier sends a notice of an appeal to the Tribunal in accordance with regulation 4 of the Health Service Medicines (Price Control Appeal) Regulations 2000(**37**), in respect of a demand made under paragraph (4), the period beginning on the date that the notice is received by the Tribunal to the date on which the appeal is finally determined or is withdrawn is discounted for the purposes of the calculation of the number of days in respect of which the manufacturer or supplier contravenes regulation 18, 19, 20, 21, 22, 23, 24 or 25 or paragraph (1) of this regulation, as the case may be.

(9) For the purposes of calculating the amount of penalty by reference to a number of days, the day on which the manufacturer or supplier starts to comply with the relevant regulation, does not count towards the calculation of that number of days.

PART 4

GENERAL PROVISIONS

Appeals

27. Any manufacturer or supplier in respect of whom the Secretary of State has made an enforcement decision(**38**) under these Regulations has a right of appeal against that decision in accordance with the Health Service Medicines (Price Control Appeal) Regulations 2000.

(**37**) S.I. 2000/124 amended by S.I. 2000/870 and 2007/1898.
(**38**) *See* section 265(7) of the 2006 Act for the definition of enforcement decision, which includes any decision relating to information that is required by virtue of an information notice under section 264A(5) of the 2006 Act.

Revocation, saving and transitional provisions

28.—(1) Subject to paragraph (2), the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007(**39**) and the 2008 Regulations are revoked.

(2) In respect of any liability of a person to pay amounts to the Secretary of State in relation to a breach of the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007 or the 2008 Regulations arising under those Regulations prior to the date of the coming into force of these Regulations, those Regulations continue to apply.

Annual review

29.—(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 the date of the coming into force of these Regulations.

Signed by the authority of the Secretary of State for Health and Social Care.

O'Shaughnessy
Parliamentary Under-Secretary of State,
Department of Health and Social Care

8th March 2018

(**39**) S.I. 2007/1320 amended by S.I. 2008/1938 and 3258, 2013/325 and 2881 and 2015/233.