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.