SCHEDULE 1 Regulation 2

Interpretation: general

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1.—(1) 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(**2**);

"the 2006 Wales Act" means the National Health Service (Wales) Act 2006(**3**);

"the 1972 Order" means the Health and Personal Social Services (Northern Ireland) Order 1972(**4**);

"the 2000 Regulations" means the Health Service Medicines (Price Control Appeals) Regulations 2000(**5**);

"the 2012 Regulations" means the Human Medicines Regulations 2012(**6**);

"common name", in relation to a medicinal product, means—

(a) the non-proprietary name of the medicinal product, or

(b) if one does not exist, the product's usual common name;

"compliance notice" has the meaning given in regulation 31(1);

"discount" means a trade or other discount (however named) and includes a settlement discount or a rebate;

"the Drug Tariff (England)" means the publication known as the Drug Tariff and published by the Secretary of State under regulation 89 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(**7**);

"the Drug Tariff (Northern Ireland)" means the publication known as the Drug Tariff and published by the Department of Health under regulation 9 of the Pharmaceutical Services Regulations (Northern Ireland) 1997(**8**);

"the Drug Tariff (Scotland)" means the Drug Tariff within the meaning given in section 27A of the 1978 Act;

"the Drug Tariff (Wales)" means the publication known as the Drug Tariff ("Tariff Cyffuriau") and published under regulation 41 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013(**9**);

"excipient", in relation to a medicinal product, means an ingredient of the product which is not an active ingredient and includes (but is not limited to)—

(a) alcohol,

(b) a colouring,

(c) a flavouring,

(d) gelatine,

(**1**) 1978 c.29.
(**2**) 2006 c. 41.
(**3**) 2006 c. 42.
(**4**) S.I. 1972/1265 (N.I. 14).
(**5**) S.I. 2000/124, amended by S.I. 2000/870, 2006/860, 2007/1898 and 2018/384.
(**6**) S.I. 2012/1916, amended by S.I. 2013/1855, 2016/186 and 2017/715; there are other amending instruments but none is relevant.
(**7**) S.I. 2013/349, to which there are amendments not relevant to these Regulations.
(**8**) S.R. 1997 No.381.
(**9**) S.I. 2013/898 (W. 102), to which there are amendments not relevant to these Regulations.

(e) gluten,

(f) lactose,

(g) a preservative, and

(h) sugar;

"excipient formulation" means a formulation in which a medicinal product is manufactured so that it may be supplied—

(a) as being free from a particular excipient,

(b) as containing a reduced amount of a particular excipient, or

(c) as containing a particular excipient,

and includes, for example, a formulation which is lactose free or which is given a specific flavour;

"financial year"—

(a) in relation to a UK primary medical services provider, Health Service chemist or an NHS hospital purchaser, has the meaning given in section 275 of the 2006 Act;

(b) in relation to any other UK producer, has the meaning given in section 390 of the Companies Act 2006(**10**);

"Health Service chemist" has the meaning given in paragraph 3(7);

"HSCIC" means the Health and Social Care Information Centre(**11**);

"importer" means a person—

(a) who is not a medicines wholesaler, but

(b) who imports health service medicines into the United Kingdom and supplies those medicines;

"imported special health service medicine" has the meaning given in regulation 10(1);

"made special health service medicine" has the meaning given in regulation 10(1);

"manufacturer's licence" has the meaning given in regulation 17 of the 2012 Regulations;

"maximum pack size"—

(a) in relation a presentation in tablet form, means a pack size of 120 tablets;

(b) in relation to a presentation in capsule form, means a pack size of 120 capsules;

(c) in relation to a presentation which is a liquid or a topical preparation, means a pack size of 500ml;

"medicines wholesaler" means a person who holds a wholesale dealer's licence (within the meaning given in regulation 18 of the 2012 Regulations);

"medical supplies wholesaler" has the meaning given in sub-paragraph (2);

"net NHS expenditure" has the meaning given in paragraph 4(2);

"net NHS wholesale income" has the meaning given in paragraph 4(3);

"net purchase amount" has the meaning given in paragraph 4(4);

"net sales income" has the meaning given in paragraph 4(5);

"NHS Digital online gateway", in relation to information required to be provided to the Secretary of State by, or under, these Regulations, means a service provided on HSCIC's website for the provision of that information;

(**10**) 2006 c. 46.

(**11**) The Health and Social Care Information Centre was established by section 252 of the Health and Social Care Act 2012 (c. 7).

"NHS framework contract" has the meaning given in paragraph 5;

"NHS hospital purchaser" means a person who—

(a) is mentioned in Part 3 of Schedule 1 to the Freedom of Information Act 2000(**12**) or in Part 4 of Schedule 1 to the Freedom of Information (Scotland) Act 2002(**13**); and

(b) is responsible, under the arrangements for managing a hospital that supplies UK health service products, for purchasing those products;

"presentation" has the meaning given in paragraph 2;

"special health service medicine" has the meaning given in regulation 10(1);

"statutory purpose" means the purpose specified in section 264A(3) of the 2006 Act;

"unbranded generic health service medicine" has the meaning given in regulation 6;

"UK primary medical services provider" has the meaning given in paragraph 3(2);

"working day" means a day which is not—

(a) a Saturday or a Sunday,

(b) Christmas Day,

(c) Good Friday, or

(d) a bank holiday in any part of the United Kingdom under the Banking and Financial Dealings Act 1971(**14**).

(2) "Medical supplies wholesaler" means a UK producer who distributes UK health service products which are not health service medicines by way of wholesale dealing.

(3) For the purposes of these Regulations, a reference to the distribution by way of wholesale dealing of UK health service products is—

(a) in the case of health service medicines to be construed in accordance with regulation 18(4) and (5) of the 2012 Regulations;

(b) in the case of any other health service products to be construed in accordance with sub-paragraph (4).

(4) A UK producer distributes a product (which is not a health service medicine) by way of wholesale dealing if the producer supplies the product to another person who buys it for the purpose of supplying it.

Meaning of "presentation of health service medicine"

2.—(1) This paragraph defines "presentation of health service medicine" and related terms for the purposes of these Regulations.

(2) "Presentation of health service medicine" means—

(a) a presentation of unbranded generic health service medicine,

(b) a presentation of made special health service medicine,

(c) a presentation of imported special health service medicine, or

(d) a presentation of any other health service medicine.

(3) "Presentation of unbranded generic health service medicine" means a particular unbranded generic health service medicine which may be distinguished from all other such medicines by reference to—

(**12**) 2000 c. 36.
(**13**) 2002 asp 13.
(**14**) 1971 c. 80.

(a) its active ingredients,

(b) its strength,

(c) its physical form,

(d) its unit dose (if applicable),

(e) its method of administration (if applicable),

(f) its freeness (if applicable),

(g) its pack size, and

(h) the type of its packaging.

(4) "Presentation of made special health service medicine" means a particular made special health service medicine which may be distinguished from all other such medicines by reference to—

(a) its active ingredients,

(b) its strength,

(c) its physical form,

(d) its unit dose (if applicable), and

(e) its method of administration (if applicable).

(5) "Presentation of imported special health service medicine" means a particular imported special health service medicine which may be distinguished from all other such medicines by reference to—

(a) its active ingredients,

(b) its strength,

(c) its physical form,

(d) its unit dose (if applicable),

(e) its method of administration (if applicable),

(f) its freeness (if applicable),

(g) its pack size, and

(h) the type of its packaging.

(6) "Presentation of other health service medicine" means a particular health service medicine which may be distinguished from all other other health service medicines by reference to—

(a) its active ingredients,

(b) its strength,

(c) its physical form,

(d) its unit dose (if applicable),

(e) its method of administration (if applicable),

(f) its freeness (if applicable),

(g) its pack size, and

(h) the type of its packaging.

(7) In paragraph (5) "other health service medicine" means a health service medicine which is not an unbranded generic health service medicine or a special health service medicine.

Meaning of "UK primary medical services provider", "Health Service chemist" and related expressions

3.—(1) This paragraph defines "UK primary medical services provider", "Health Service chemist" and related expressions for the purposes of these Regulations.

(2) "UK primary medical services provider" means a person who—

(a) provides primary medical services under Part 4 of the 2006 Act,

(b) provides primary medical services under Part 4 of the 2006 Wales Act,

(c) provides primary medical services—

(i) under section 2C(1) of the 1978 Act,

(ii) under an agreement under section 17C of that Act, or

(iii) under a contract under section 17J of that Act, or

(d) provides primary medical services under Part 2 or 6 of the 1972 Order.

(3) "Health Service chemist" means—

(a) an English NHS chemist,

(b) a Welsh NHS chemist,

(c) a Scottish NHS chemist, or

(d) a Northern Ireland HS chemist.

(4) "English NHS chemist" means a person (other than a primary medical services provider) who provides pharmaceutical or local pharmaceutical services under Part 7 of the 2006 Act.

(5) "Welsh NHS chemist" means a person (other than a primary medical services provider) who provides pharmaceutical services under Part 7 of the 2006 Wales Act.

(6) "Scottish NHS chemist" means a person (other than a primary medical services provider) who provides pharmaceutical care services under section 2CA(1) of the 1978 Act.

(7) "Northern Ireland HS chemist" means a person (other than a primary medical services provider) who provides pharmaceutical services under Part 2 or 6 of the 1972 Order.

Meaning of "net NHS expenditure", "net NHS wholesale income", "net purchase amount" and "net sales income"

4.—(1) This paragraph defines "net NHS expenditure", "net NHS wholesale income", "net purchase amount" and "net sales income" for the purposes of these Regulations.

(2) "Net NHS expenditure" means the total amount paid (in pounds sterling) by a UK producer for UK health service products—

(a) excluding value added taxes, and

(b) after the deduction of—

(i) all discounts and payments, and,

(ii) the value of all payments or benefits in kind,

received in connection with the purchase of those products;

(3) "Net NHS wholesale income" means a UK producer's total income (in pounds sterling) from the distribution by way of wholesale dealing of UK health service products—

(a) excluding value added taxes, and

(b) after the deduction of—

(i) all discounts and payments, and

(ii) the value of all payments or benefits in kind,

given in connection with the supply of those products.

(4) "Net purchase amount", in relation to the purchase of a health service product by a UK producer, means the amount paid (in pounds sterling) by the producer for the product—

(a) including any delivery or supply charge (however named) paid in connection with the purchase, but

(b) after the deduction of—

(i) all discounts and payments, and

(ii) the value of all payments or benefits in kind,

received in connection with the purchase.

(5) "Net sales income", in relation to the supply of a health service product by a UK producer, means the producer's income (in pounds sterling) from the supply of the product—

(a) including any delivery or supply charge (however named) charged in connection with the supply, but

(b) excluding value added taxes, and

(c) after the deduction of—

(i) all discounts and payments, and

(ii) the value of all payments or benefits in kind,

given in connection with the supply.

(6) For the purposes of sub-paragraphs (2) to (5), it does not matter whether a discount, payment, payment or benefit in kind can be attributed to the supply or, as the case may be, purchase of a particular health service product.

Meaning of "NHS framework contract"

5.—(1) In these Regulations, "NHS framework contract" means—

(a) a contract with a contracting authority which is based on a framework agreement concluded under the 2006 Regulations, the 2012 Scotland Regulations, the 2015 Regulations or the 2015 Scotland Regulations, or

(b) a public contract awarded under the 2006 Regulations, the 2012 Scotland Regulations, the 2015 Regulations or the 2015 Scotland Regulations;

(2) For the purposes of sub-paragraph (1)—

"the 2006 Regulations" means the Public Contracts Regulations 2006(**15**);

"the 2012 Scotland Regulations" means the Public Contracts (Scotland) Regulations 2012(**16**);

"the 2015 Regulations" means the Public Contracts Regulations 2015(**17**);

"the 2015 Scotland Regulations" means the Public Contracts (Scotland) Regulations 2015(**18**);

"contracting authority", in relation to a contract based on a framework agreement—

(a) where the framework agreement was concluded under the 2006 Regulations, has the meaning given in regulation 3 of those Regulations;

(**15**) S.I. 2006/5; the Regulations were revoked, subject to transitional provisions, by the Public Contracts Regulations 2015 (S.I. 2015/102), regulation 116.
(**16**) S.S.I. 2012/88; the Regulations were revoked, subject to transitional provisions, by the Public Contracts (Scotland) Regulations 2015 (S.S.I/446), regulation 97.
(**17**) S.I. 2015/102, to which there are amendments not relevant to these Regulations.
(**18**) S.S.I. 2015/446, to which there are amendments not relevant to these Regulations.

(b) where the framework agreement was concluded under the 2012 Scotland Regulations, has the meaning given in regulation 3 of those Regulations;

(c) where the framework agreement was concluded under the 2015 Regulations, has the meaning given in regulation 2 of those Regulations;

(d) where the framework agreement was concluded under the 2015 Scotland Regulations, has the meaning given in regulation 2 of those Regulations.

Interpretation: listing of an appliance in a Drug Tariff

6.—(1) For the purposes of these Regulations, an appliance is listed in a Drug Tariff if the appliance is listed—

(a) in Part IX of the Drug Tariff (England) for the given month,

(b) in Part IX of the Drug Tariff (Wales) for the given month,

(c) in Part II, VI or IX of the Drug Tariff (Scotland) for the given month, or

(d) in Part III of the Drug Tariff (Northern Ireland) for the given month.