SCHEDULE 1 Regulation 2

Interpretation: general

Interpretation: general

1.—(1) In these Regulations—

"the 1978 Act" means the National Health Service (Scotland) Act 1978 [M1];

"the 2006 Act" means the National Health Service Act 2006 [M2];

"the 2006 Wales Act" means the National Health Service (Wales) Act 2006 [M3];

"the 1972 Order" means the Health and Personal Social Services (Northern Ireland) Order 1972 [M4];

"the 2000 Regulations" means the Health Service Medicines (Price Control Appeals) Regulations 2000 [M5];

"the 2012 Regulations" means the Human Medicines Regulations 2012 [M6];

"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 [M7];

"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 [M8];

"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 [M9];

"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,

(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 [M10];

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

[F1]...

"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);

[F1]...

[[F2]"NHS England" means the body corporate established under section 1H of the National Health Service Act 2006;**]**

[[F2]"NHS England 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 NHS England's website for the provision of that information;

"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 [M11] or in Part 4 of Schedule 1 to the Freedom of Information (Scotland) Act 2002 [M12]; 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 [M13].

(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.**]**

Textual Amendments

F1 Words in Sch. 1 para. 1(1) omitted (1.2.2023) by virtue of The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98), reg. 1(2), **Sch. para. 58(7)(b)** (with reg. 3)

F2 Words in Sch. 1 para. 1(1) inserted (1.2.2023) by The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98), reg. 1(2), **Sch. para. 58(7)(a)** (with reg. 3)

Marginal Citations

M1 1978 c.29.

M2 2006 c. 41.

M3 2006 c. 42.

M4 S.I. 1972/1265 (N.I. 14).

M5 S.I. 2000/124, amended by S.I. 2000/870, 2006/860, 2007/1898 and 2018/384.

M6 S.I. 2012/1916, amended by S.I. 2013/1855, 2016/186 and 2017/715; there are other amending instruments but none is relevant.

M7 S.I. 2013/349, to which there are amendments not relevant to these Regulations.

M8 S.R. 1997 No.381.

M9 S.I. 2013/898 (W. 102), to which there are amendments not relevant to these Regulations.
M10 2006 c. 46.
M11 2000 c. 36.
M12 2002 asp 13.
M13 1971 c. 80.

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—

(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 [M14];

"the 2012 Scotland Regulations" means the Public Contracts (Scotland) Regulations 2012 [M15];

"the 2015 Regulations" means the Public Contracts Regulations 2015 [M16];

"the 2015 Scotland Regulations" means the Public Contracts (Scotland) Regulations 2015 [M17];

"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;

(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.

Marginal Citations

M14 S.I. 2006/5; the Regulations were revoked, subject to transitional provisions, by the Public Contracts Regulations 2015 (S.I. 2015/102), **regulation 116**.

M15 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.

M16 S.I. 2015/102, to which there are amendments not relevant to these Regulations.

M17 S.S.I. 2015/446, to which there are amendments not relevant to these 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.

SCHEDULE 2

Regulations 24, 31 and 32

Small producers

General

1. This Schedule sets out the rules for determining whether a UK producer is a small producer for the purposes of regulation 24, 31 or 32.

Interpretation of Schedule 2

2.—(1) In this Schedule—

"net NHS sales income", in relation to a producer, means the producer's total income (in pounds sterling) from the supply 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;

"pharmaceutical services remuneration"—

(a) in relation to a Health Service chemist who is an English NHS chemist, means remuneration for the provision of pharmaceutical or local pharmaceutical services under Part 7 of the 2006 Act;

(b) in relation to a Health Service chemist who is a Welsh NHS chemist, means remuneration for the provision of pharmaceutical services under Part **7** of the 2006 Wales Act;

(c) in relation to a Health Service chemist who is a Scottish NHS chemist, means remuneration for the provision of pharmaceutical care services under section 2CA(1) of the 1978 Act;

(d) in relation to a Health Service chemist who a Northern Ireland HS chemist, means remuneration for the provision of pharmaceutical services under Part 2 or 6 of the 1972 Order;

"qualifying Health service chemist" means a Health Service chemist who, in the relevant financial year, is paid pharmaceutical services remuneration of £5 million or less;

"qualifying NHS hospital purchaser" means a NHS hospital purchaser who, in the relevant financial year, has net NHS expenditure of £5 million or less.

(2) For the purposes of this Schedule, "the relevant financial year"—

(a) in relation to a UK producer who receives a request under regulation 23, means the producer's last complete financial year ending before the day on which the producer is given the request;

(b) in relation to a UK producer who—

(i) is given a compliance notice relating to an original request given under regulation 23, or

(ii) is liable to pay a penalty under regulation 32(4) for failing to comply with such a notice,

means the producer's last complete financial year ending before the day on which the producer was given the original request under regulation 23;

(c) in relation to a UK producer who is liable to pay a penalty under regulation 32(4)—

(i) for failing to comply with regulation 25(4), or

(ii) in connection with a compliance notice other than one mentioned in paragraph (b)(i),

means the last complete financial year ending before the day on which the producer becomes liable to pay the penalty.

UK primary medical providers who are small producers

3. A UK producer who is a UK primary medical services provider is a small producer if—

(a) the producer is not also a medicines wholesaler or a medical supplies wholesaler, or

(b) the producer—

(i) is a medicines wholesaler or a medical supplies wholesaler, but

(ii) in the relevant financial year, has net NHS wholesale income of £5 million or less.

Health Service chemists who are small producers

4. A UK producer who is a qualifying Health Service chemist is a small producer if—

(a) the producer is not also a medicines wholesaler or a medical supplies wholesaler, or

(b) the producer—

(i) is a medicines wholesaler or a medical supplies wholesaler, but

(ii) in the relevant financial year, has net NHS wholesale income of £5 million or less.

NHS hospital purchasers who are small producers

5. A UK producer who is a qualifying NHS hospital purchaser is a small producer if—

(a) the producer is not also a medicines wholesaler or a medical supplies wholesaler, or

(b) the producer—

(i) is a medicines wholesaler or a medical supplies wholesaler, but

(ii) in the relevant financial year, has net NHS wholesale income of £5 million or less.

Other UK producers who are small producers

6.—(1) A UK producer who is not a UK primary medical services provider, a Health Service chemist or an NHS hospital purchaser is a small producer if—

(a) the producer has net NHS sales income of £5 million or less in the relevant financial year,

(b) the producer receives—

(i) a request under regulation 23 during the producer's first accounting reference period, or

(ii) a compliance notice in connection with such a request, or

(c) the producer becomes liable to pay a penalty under regulation 32(4) during the producer's first accounting reference period.

(2) In this paragraph, "accounting reference period" had the meaning given in section 391 of the Companies Act 2006.

SCHEDULE 3

Regulation 32

Calculation of daily penalty

Interpretation of Schedule 3

1.—(1) In this Schedule, "net NHS sales income", "qualifying Health Service chemist" and "qualifying NHS hospital purchaser" have the meanings given in paragraph 2 of Schedule 2.

(2) In this Schedule, "relevant financial year"

(a) in relation to a UK producer who is liable to pay a penalty under regulation 32(4) for failing to comply with a compliance notice relating to an original request under regulation 23, means the producer's last complete financial year ending before the day on which the producer was given the original request;

(b) in relation to a UK producer who is liable to pay a penalty under regulation 32(4) for any other reason, means the last complete financial year ending before the day on which the producer is given the penalty demand.

Daily penalty payable by UK producers who are small producers

2. The daily penalty payable by a UK producer who is a small producer is—

(a) £250 per day for—

(i) the day on which the contravention occurs, and

(ii) each of the next following 13 days on which the contravention continues;

(b) £500 per day for the fifteenth day and each subsequent day on which the contravention continues.

Daily penalty payable by UK producers who are not small producers

3.—(1) The daily penalty payable by a UK producer who is not a small producer is—

(a) the column 2 amount per day for—

(i) the day on which the contravention occurs, and

(ii) each of the next following 13 days on which the contravention continues;

(b) the column 3 amount per day for the fifteenth and each subsequent day on which the contravention continues.

(2) In this paragraph—

"column 2 amount", in relation to a producer, means the amount specified in column 2 of the Table which corresponds to the relevant financial threshold;

"column 3 amount", in relation to a producer, means the amount specified in column 3 of the Table which corresponds to the relevant financial threshold;

"relevant financial threshold", in relation to a producer, means the financial threshold specified in column 1 of the Table into which the producer's relevant income falls.

(3) For the purposes of this paragraph, a producer's relevant income is—

(a) the producer's net NHS wholesale income in the relevant financial year, if—

(i) the producer is a primary medical services provider,

(ii) the producer is a Health Service chemist and—

(aa) is also a medicines wholesaler or a medical supplies wholesaler, and

(bb) in the relevant financial year, is paid pharmaceutical services remuneration of an amount less than the producer's net NHS wholesale income in that year, or

(iii) the producer is an NHS hospital purchaser and—

(aa) is also a medicines wholesaler or a medical supplies wholesaler, and

(bb) in the relevant financial year, has net NHS expenditure of an amount less than the producer's net NHS wholesale income;

(b) the producer's pharmaceutical services remuneration in the relevant financial year, if the producer is a Health Service chemist and either—

(i) is not a medicines wholesaler or a medical supplies wholesaler, or

(ii) is a medicines wholesaler or a medical supplies wholesaler with net NHS wholesale income in the relevant financial year which is equal to or less than the amount the producer is paid as pharmaceutical service remuneration in that year;

(c) the producer's net NHS expenditure in the relevant financial year, if the producer is an NHS hospital purchaser and either—

(i) is not a medicines wholesaler or a medical supplies wholesaler, or

(ii) is a medicines wholesaler or a medical supplies wholesaler with net NHS wholesale income in the relevant financial year which is equal to or less than the producer's net NHS expenditure in that year;

(d) the producer's net NHS sales income in the relevant financial year, if the producer is not a UK primary medical services provider, a UK NHS chemist or an NHS hospital purchaser.

(4) But where the Secretary of State cannot reasonably determine a producer's net NHS sales income for the relevant financial year, the producer's relevant income for that year is the producer's total UK sales for that year.

(5) For the purposes of sub-paragraph (4), a producer's total UK sales are the total sales in the United Kingdom as shown in—

(a) the producer's statutory audited accounts for the relevant financial year, or

(b) if the producer does not have those accounts, the producer's individual accounts for the most recent complete financial year.

(6) In this paragraph—

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

"statutory audited accounts"—

(a) in relation to a producer whose individual accounts are required to be audited in accordance with Part 16 of the Companies Act 2006, means the producer's individual accounts audited in accordance with that Part;

(b) in relation to a producer whose individual accounts are exempt under section 477 of the Companies Act 2006 from audit under Part 16 of that Act, means the producer's individual accounts;

(c) in relation to a producer whose accounts individual accounts are exempt under section 479A of the Companies Act 2006 from audit under Part 16 of that Act, means the consolidated accounts of the parent undertaking on the same group as the producer (see section 479A(2)(a) of that Act).

Column 1 – financial threshold	***Column 2 – daily penalty: first 14 days***	***Column 3 – daily penalty: fifteenth and subsequent days***

more than £5,000,000 but less than £20,000,000	£500	£1,000
£20,000,000 or more but less than £50,000,000	£1,000	£2,000
£50,000,000 or more but less than £100,000,000	£2,500	£5,000
£100,000,000 or more	£5,000	£10,000

SCHEDULE 4

Regulation 34

Disclosure of information under section 246B of the 2006 Act: prescribed bodies and prescribed purposes

1.—(1) The bodies specified in column 1 of Table 1, being bodies appearing to the Secretary of State to represent UK producers, are prescribed for the purposes of section 264B(1)(k) of the 2006 Act.

(2) The purpose for which a body specified in column 1 of Table 1 may use confidential or commercially sensitive information disclosed to it under section 264B(1) of the 2006 Act is the purpose prescribed in the corresponding entry in column 2 of that Table.

Table 1

Column 1 – Bodies	***Column 2 – The purpose for which information disclosed under section 264B(1) of the 2006 Act may be used***
Association of British Healthcare Industries; Association of Pharmaceutical Specials Manufacturers; British Association of European Pharmaceutical Distributors; British Generic Manufacturers Association; British Healthcare Trades Association; British In Vitro Diagnostics Association; Healthcare Distribution Association; NHS Pharmacy Production Committee; NHS Pharmaceutical Quality Assurance; Proprietary Association of Great Britain; Surgical Dressings Manufacturers Association Committee; Urology Trade Association.	The purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(a) to (l).
Association of Independent Multiple Pharmacies; Company Chemists' Association; National Pharmacy Association.	The purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(a) to (k).
BioIndustry Association; Ethical Medicines Industry Group.	The purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(c), (e), (g), (i), (l) and (m).

Association of the British Pharmaceutical Industry	The purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(c), (e), (g), (i) and (k) to (m).
British Medical Association; Dispensing Doctor's Association.	The purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(a), (c), (d), (f), (g) and (i) to (k).
Pharmaceutical Services Negotiating Committee	The purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(b) and (c).

2.—(1) The bodies specified in column 1 of Table 2 are prescribed for the purposes of section 264B(1)(l) of the 2006 Act.

(2) The purpose for which a body specified in column 1 of Table 2 may use confidential or commercially sensitive information disclosed to it under section 264B(1) of the 2006 Act is the purpose prescribed in the corresponding entry in column 2 of that Table.

Table 2

Column 1 – Bodies	***Column 2 – Purpose for which information disclosed under section 264B(1) of the 2006 Act may be used***
Any NHS foundation trust; Any NHS trust established under the 2006 Act; Any **[**[F3]integrated care board**]**.	The purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(c).
Any NHS trust established under the 2006 Wales Act; Any Local Health Board.	The purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(f).
Any Health Board constituted under section 2 of the 1978 Act	The purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(i).
The Regional Health and Social Care Board established under section 7 of the Health and Social Care (Reform) Act Northern Ireland 2009 **M18**	The purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(k).

Textual Amendments

F3 Words in Regulations substituted (1.7.2022) by The Health and Care Act 2022 (Consequential and Related Amendments and Transitional Provisions) Regulations 2022 (S.I. 2022/634), reg. 1(2), Sch. para. 1(1)**(3)** (with Sch. para. 1(2))

Marginal Citations

M18 2009 c. 1 (N.I.)

SCHEDULE 5

Regulation 35(2)

Information about supply of unbranded generic health service medicines or special health service medicines: transitional provisions

General

1. This Schedule makes transitional provision in relation to—

(a) the recording, keeping and provision of information about the supply of unbranded generic health service medicines by members of Scheme M and Scheme W (see paragraphs 2 and 3), and

(b) the recording, keeping and provision of information about the supply of special health service medicines by members of the Specials MoU (see paragraphs 4 and 5).

Transitional provision: information about supply of unbranded generic health service medicines

2.—(1) A Scheme member is not required to comply—

(a) with regulation 7 or 8 in any month which falls within a transitional quarter, or

(b) with regulation 9 in respect of any transitional quarter.

(2) But this paragraph is subject to paragraph 3.

(3) In this paragraph and paragraph 3—

"Scheme end date" means—

(a) in the case of a member of Scheme M, the day on which Scheme M ceases to operate following notice of termination being given by the Secretary of State in accordance with that Scheme;

(b) in the case of a member of Scheme W, the day on which Scheme W ceases to operate following notice of termination being given by the Secretary of State in accordance with that Scheme;

"Scheme member" means a UK producer who, immediately before 1st July 2018, is a member of Scheme M or Scheme W;

"transitional quarter" means a quarterly period (as determined in accordance with regulation 9(2)) which—

(a) begins on or after 1st July 2018, but

(b) before the Scheme end date.

(4) For the purposes of this paragraph, it does not matter whether the Secretary of State gives notice of termination in accordance with Scheme M or Scheme W before, on or after 1st July 2018.

Circumstances in which transitional provision in paragraph 2 ceases to apply

3.—(1) This paragraph applies to a Scheme member—

(a) who does not provide the Scheme information to the Secretary of State for a Scheme quarter within the submission period, or

(b) who, before the Scheme end date, ceases to be a member of the Scheme.

Such a member is referred to in this paragraph as an "exiting member".

(2) An exiting member must comply with regulation 7 or 8 (or both, as the case may be) on and after the exit date.

(3) An exiting member must also comply with regulation 9 in respect of each transitional quarter which begins on or after the exit date.

(4) In addition, where the exit date falls during a transitional quarter, the exiting member must comply with regulation 9 in respect of the remaining part of that quarter.

(5) In this regulation—

"exit date"—

(a) in relation to an exiting member to whom sub-paragraph (1)(a) applies, means the day after the day on which the submission period ends;

(b) in relation to an exiting member to whom sub-paragraph (1)(b) applies, means the day on which the member ceases to be a member of the Scheme;

"Scheme information" means—

(a) in the case of a member of Scheme M, the information which the member is required under Scheme M to provide to the Secretary of State for each Scheme quarter;

(b) in the case of a member of Scheme W, the information which the member is required under Scheme W to provide to the Secretary of State for each Scheme quarter;

"Scheme quarter"—

(a) in the case of a member of Scheme M, means a quarterly period—

(i) which is specified in that Scheme as a period for which Scheme information is to be provided, and

(ii) for which the submission period ends after 1st July 2018;

(b) in the case of a member of Scheme W, means a quarterly period—

(i) which is specified in that Scheme as a period for which Scheme information is to be provided, and

(ii) for which the submission period ends after 1st July 2018;

"submission period" means the period within which Scheme information must be submitted following the end of a Scheme quarter.

Transitional provision: information about supply of special health service medicines

4.—(1) A Specials MoU member is not required to comply—

(a) with regulation 11, 12 or 13 in any month which falls within a transitional quarter, or

(b) with regulation 14 in respect of any transitional quarter.

(2) But this paragraph is subject to paragraph 5.

(3) In this paragraph and paragraph 5—

"Specials MoU end date" means the day on which the Specials MoU ceases to operate following notice of termination being given by the Secretary of State in accordance with the MoU;

"Specials MoU member" means a UK producer who, immediately before 1st August 2018, is a participating manufacturer for the purposes of the Specials MoU;

"transitional quarter" means a quarterly period (determined in accordance with regulation 14(2)) which begins—

(a) on or after 1st August 2018, but

(b) before the day on which the Specials MoU end date.

(4) For the purposes of this paragraph, it does not matter whether the Secretary of State gives notice of termination in accordance with the Specials MoU before, on or after 1st August 2018.

Circumstances in which transitional provision in paragraph 4 ceases to apply

5.—(1) This regulation applies to a Specials MoU member—

(a) who does not provide the specials information to the Secretary of State for an MoU quarter within the submission period; or

(b) who, before the Specials MoU end date, ceases to be a Specials MoU member.

Such a member is referred to in this paragraph as an "exiting member".

(2) An exiting member must comply with regulations 11, 12 and 13 on and after the exit date.

(3) An exiting member must comply with regulation 14 in respect of each transitional quarter which begins on or after the exit date.

(4) In addition, where the exit date falls during a transitional quarter, the exiting member must comply with regulation 14 in respect of the remaining part of that quarter.

(5) In this regulation—

"exit date"—

(a) in relation to an exiting member to whom sub-paragraph (1)(a) applies, means the day after the day on which the submission period ends;

(b) in relation to an exiting member to whom sub-paragraph (1)(b) applies, means the day on which the member ceases to be a member;

"MoU quarter" means a quarterly period—

(a) which is specified in the Specials MoU as a period for which specials information is to be provided, and

(b) for which the submission period ends after 1st August 2018;

"specials information" means the information which a Specials MoU member is required under the Specials MoU to provide to the Secretary of State in respect of each MoU quarter;

"submission period" means the period within which the specials information must be provided to the Secretary of State following the end of the relevant MoU quarter.

Changes to legislation:
There are currently no known outstanding effects for the The Health Service Products (Provision and Disclosure of Information) Regulations 2018.