STATUTORY INSTRUMENTS

2018 No. 677

NATIONAL HEALTH SERVICE, ENGLAND AND WALES
NATIONAL HEALTH SERVICE, SCOTLAND
HEALTH AND PERSONAL SOCIAL SERVICES, NORTHERN IRELAND

The Health Service Products (Provision and Disclosure of Information) Regulations 2018

Made - - - -	*5th June 2018*
Laid before Parliament	*8th June 2018*
Coming into force in accordance with regulation 1	

The Secretary of State for Health and Social Care makes the following Regulations in exercise of the powers conferred by sections 264A(2), (5) and (7), 264B(1)(k) and (l) and (3)(g), 265(1), (5)(b) and (5A) and 272(7) and (8) of the National Health Service Act 2006 [F1].

The Secretary of State, in accordance with sections 264C(1) and 265(9) of that Act [F2], has consulted the industry body and such other bodies appearing to the Secretary of State appropriate to represent UK producers.

F1 2006 c. 41; sections 264A and 264B were inserted by the Health Services Medical Supplies (Costs) Act 2017 (c. 23) ("the 2017 Act"), section 8. Section 265(5) was amended by the 2017 Act, section 10(9). Section 265(5A) was inserted by the 2017 Act, section 10(10). See section 275(1) of the National Health Service Act 2006 for the definition of "prescribed" and "regulations".

F2 Section 264C was inserted by the Health Services Medical Supplies (Costs) Act 2017, section 8. Section 265(9) was substituted by the Health Services Medical Supplies (Costs) Act 2017, section 10(13).

PART 1

Introductory

Citation and commencement

1.—(1) These Regulations may be cited as the Health Service Products (Provision and Disclosure of Information) Regulations 2018.

(2) Subject to paragraphs (3) and (4), these Regulations come into force on 1st July 2018.

(3) Part 3 comes into force on 1st August 2018.

(4) Regulation 29 comes into force on 1st January 2019.

Interpretation: general

2. These Regulations are to be interpreted in accordance with Schedule 1.

Application

3. Nothing in these Regulations—

(a) requires a person who provides primary medical services under Part 4 of the 2006 Wales Act, or any person who provides services under Part 7 of that Act, to record, keep or provide information relating to any Welsh health service products [F3] which are supplied by the person in providing the services in question;

(b) requires a person who provides primary medical services under section 2C(1) of the 1978 Act, or any person who provides pharmaceutical care services under section 2CA(1) of that Act, to record, keep or provide any information relating to any Scottish health service products [F4] which are supplied by the person in providing the services in question;

(c) requires a person who provides primary medical services or pharmaceutical services under Part 2 or 6 of the 1972 Order to record, keep or provide information about Northern Ireland health service products [F5] which are supplied by the person in providing the services in question.

F3 See the definition of "Welsh health service products" in section 264A(15) of the National Health Service Act 2006.

F4 See the definition of "Scottish health service products" in section 264A(13) of the National Health Service Act 2006.

F5 See the definition of "Northern Ireland health service products" in section 264A(12) of the National Health Service Act 2006.

Exception: products not known to be health service products

4. Nothing in these Regulations requires a UK producer [F6] to record and keep, or provide, information about a product if the producer could not reasonably have known, at the time the producer purchased or supplied the product, that it was, or was to be, a UK health service product [F7].

F6 See the definition of "UK producer" in section 264A(1) of the National Health Service Act 2006.

F7 See the definition of "UK health service products" in section 264A(14) of the National Health Service Act 2006.

Information required to be provided via an [F8NHS England] online gateway

5.—(1) This regulation applies where a question arises as to whether any information required to be provided by, or under, these Regulations electronically via an **[**F8NHS England**]** online gateway has been so provided.

(2) For the purposes of these Regulations, it is to be presumed—

(a) that the relevant information has been successfully provided electronically via the relevant online gateway only if **[**F8NHS England**]** has successfully recorded the information;

(b) that the relevant information was provided at the time it was recorded by **[**F8NHS England**]**;

(c) that the person providing the information is the person identified as such by the information recorded by **[**F8NHS England**]**;

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

(3) The presumptions in paragraph (2) are rebuttable.

F8 Words in reg. 5 substituted (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(2)** (with reg. 3)

PART 2

Quarterly information about unbranded generic health service medicines

Meaning of "unbranded generic health service medicine" and listing of a presentation of unbranded generic health service medicine

6.—(1) In these Regulations, "unbranded generic health service medicine" means a health service medicine F9 the labelling of which includes the common name of the product, but does not include an invented name.

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

"invented name" means a name which—

(a) is not the common name of the medicinal product, and

(b) is not liable to be confused with that name;

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

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

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

(c) a British Approved Name (BAN),

(d) a British Approved Name Modified (BANM), or

(e) an approved name.

(3) The names mentioned in paragraphs (a) to (e) of the definition of "non-proprietary name" (and their permitted variations) have the same meanings as in a list of names which has been prepared and published under regulation 318 of the 2012 Regulations and which is in force F10.

(4) For the purposes of this Part, a presentation of unbranded generic health service medicine is listed in a Drug Tariff if a price for that presentation is listed—

(a) in the Drug Tariff (England) F11 for the given month,

(b) in the Drug Tariff (Wales) [F12] for the given month,

(c) in the Drug Tariff (Scotland) [F13] for the given month, or

(d) in the Drug Tariff (Northern Ireland) [F14] for the given month.

(5) For the purposes of determining whether a reimbursement price is listed for a presentation, any pack size specified in the relevant Drug Tariff is to be disregarded.

F9 See section 266(6) of the National Health Service Act 2006 for the definition of "health service medicine".

F10 Copies of the list can be obtained from: https://www.pharmacopoeia.com/what-is-the-ban-book or The Stationery Office, PO Box 29, Norwich, NR3 1GN.

F11 The Drug Tariff (England) is available at https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff or from NHS Business Services Authority, Stella House, Goldcrest Way, Newburn Riverside, Newcastle upon Tyne, NEI5 8NY.

F12 The Drug Tariff (Wales) is available at https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff or from NHS Business Services Authority, Stella House, Goldcrest Way, Newburn Riverside, Newcastle upon Tyne, NEI5 8NY.

F13 The Drug Tariff (Scotland) is available at http://www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/Scottish-Drug-Tariff/ or from Information Services Division, NHS National Services Scotland, Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB.

F14 The Drug Tariff (Northern Ireland) is available at http://www.hscbusiness.hscni.net/services/2034.htm or from Business Services Organisation Headquarters, 2 Franklin Street Belfast, BT2 8DQ.

Information to be recorded and kept about supply of unbranded generic health service medicines: manufacturers and importers

7.—(1) A relevant producer must record the information mentioned in paragraph (3) for each presentation of unbranded generic health service medicine which—

(a) the producer manufactures, or imports, and supplies to any of the following—

(i) a UK primary medical services provider,

(ii) a Health Service chemist, or

(iii) a medicines wholesaler,

(b) is, in the month in which the producer supplies it, listed in a Drug Tariff, and

(c) if it is a liquid or a topical preparation**,** or is in tablet or capsule form, is in a pack not exceeding the maximum pack size.

(2) The relevant producer must keep the information recorded under paragraph (1) until it is provided to the Secretary of State in accordance with regulation 9.

(3) The information is—

(a) the number of packs supplied to persons mentioned in paragraph (1)(a)(i) to (iii), and

(b) the net sales income, or a reasonable estimate of the net sales income, from that supply.

(4) In this regulation, "relevant producer" means—

(a) a manufacturer [F15], or

(b) a UK producer who is an importer.

F15 See section 266(6) of the National Health Service Act 2006 (c. 41) for the definition of "manufacturer".

Information to be recorded and kept about supply of unbranded generic health service medicines: medicines wholesalers

8.—(1) A UK producer who is a medicines wholesaler must—

(a) record the information mentioned in paragraph (2) for each presentation of unbranded generic health service medicine which the producer purchases for supply (including any purchase which requires the presentation to be imported into the United Kingdom) and—

(i) which is, in the month in which producer purchases it, listed in a Drug Tariff, and

(ii) if it is a liquid or a topical preparation**,** or is in tablet or capsule form, which is in a pack not exceeding the maximum pack size, and

(b) keep that information until it is provided to the Secretary of State in accordance with regulation 9.

(2) The information is—

(a) the number of packs purchased, and

(b) the net purchase amount, or a reasonable estimate of the net purchase amount, for that purchase.

(3) A UK producer who is a medicines wholesaler must also—

(a) record the information mentioned in paragraph (4) for each presentation of unbranded generic health service medicine (other than a presentation which the wholesaler has manufactured) which—

(i) the producer supplies to any UK primary medical services provider or Health Service chemist,

(ii) is, in the month in which the producer supplies it, listed in a Drug Tariff, and

(iii) if it is a liquid or a topical preparation**,** or is in tablet or capsule form, is in a pack which does not exceed the maximum pack size, and

(b) keep that information until it is provided to the Secretary of State in accordance with regulation 9.

(4) The information is—

(a) the number of packs supplied to persons mentioned in paragraph (3)(a)(i), and

(b) the net sales income, or a reasonable estimate of the net sales income, from that supply.

Requirement to provide information about supply of unbranded generic health service medicines

9.—(1) A UK producer must provide the information which the producer is required to record and keep under regulation 7 or 8 to the Secretary of State in accordance with this regulation.

(2) The information must be provided, in each year, for the following quarterly periods—

(a) 1st July to 30th September;

(b) 1st October to 31st December;

(c) 1st January to 31st March;

(d) 1st April to 30th June.

(3) The information for a quarterly period must be provided—

(a) in an electronic spreadsheet provided for that purpose by the Secretary of State, or

(b) if the Secretary of State does not provide such a spreadsheet, via the **[**[F16]NHS England**]** online gateway.

(4) The information for a quarterly period must be provided within the period of 28 days beginning with the first day of the month which begins immediately after the end of that quarterly period.

F16 Words in reg. 9(3)(b) substituted (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(3)** (with reg. 3)

PART 3

Quarterly information about special health service medicines

Meaning of "special health service medicine", "imported special health service medicine", "made special health service medicine" and listing of a presentation of special health service medicine in a Drug Tariff

10.—(1) In these Regulations—

"imported special health service medicine" means a special health service medicine which is imported into the United Kingdom;

"made special health service medicine" means a special health service medicine which is manufactured in the United Kingdom;

"special health service medicine" means a health service medicine which is a special medicinal product (within the meaning of regulation 167 [F17] of the 2012 Regulations).

(2) For the purposes of this Part, a presentation of special health service medicine is listed in a Drug Tariff if a price for that presentation is listed—

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

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

(c) in the Drug Tariff (Scotland) for the given month, or

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

(3) For the purposes of determining whether a reimbursement price is listed for a presentation, any pack size specified in the relevant Drug Tariff is to be disregarded.

F17 Regulation 167 of the 2012 Regulations was amended by S.I. 2017/715.

Information to be recorded about supply of made special health service medicines: manufacturers

11.—(1) A manufacturer must record the information mentioned in paragraph (3) for each presentation of made special health service medicine which—

(a) the manufacturer manufactures and supplies to any of the following—

(i) a UK primary medical services provider,

(ii) a Health Service chemist, or

(iii) a medicines wholesaler, and

(b) is, in the month in which the manufacturer supplies it, listed in a Drug Tariff.

(2) A manufacturer must keep the information recorded under paragraph (1) until it is provided to the Secretary of State in accordance with regulation 14.

(3) The information is—

(a) the type of manufacture,

(b) the excipient formulations (if any),

(c) the quantity, by pack size, supplied to the persons mentioned in paragraph (1)(a)(i) to (iii), and

(d) the net sales income, or a reasonable estimate of the net sales income, from the supply.

Information to be recorded about supply of made special health service medicines: medicines wholesalers

12.—(1) A UK producer who is a medicines wholesaler must—

(a) record the information mentioned in paragraph (2) for each presentation of made special health service medicine which—

(i) the wholesaler purchases for supply, and

(ii) is, in the month in which the wholesaler purchases it, listed in a Drug Tariff, and

(b) keep that information until it is provided to the Secretary of State in accordance with regulation 14.

(2) The information is—

(a) the quantity, by pack size, purchased,

(b) the excipient formulations purchased (if any), and

(c) the net purchase amount, or a reasonable estimate of the net purchase amount, for the purchase.

(3) A UK producer who is a medicines wholesaler must also—

(a) record the information mentioned in paragraph (4) for each presentation of made special health service medicine (other than a presentation of such medicine which the wholesaler has manufactured) which—

(i) the producer supplies to any UK primary medical services provider or Health Service chemist, and

(ii) is, in the month in which the wholesaler supplies it, listed in a Drug Tariff, and

(b) keep that information until it is provided to the Secretary of State in accordance with regulation 14.

(4) The information is—

(a) the quantity, by pack size, supplied,

(b) the excipient formulations supplied (if any), and

(c) the net sales income, or a reasonable estimate of the net sales income, from the supply.

Information to be recorded and kept about supply of imported special health service medicines: medicines wholesalers and importers

13.—(1) A UK producer who is a medicines wholesaler or an importer must—

(a) record and keep the information mentioned in paragraph (2) for each presentation of imported special health service medicine—

(i) which the producer purchases for supply, and

(ii) which is, in the month in which the producer purchases it, listed in a Drug Tariff, and

(b) keep that information until it is provided to the Secretary of State in accordance with regulation 14.

(2) The information for a presentation is—

(a) the number of packs purchased, and

(b) the net purchase amount paid, or a reasonable estimate of the net purchase amount paid, for that purchase.

(3) A UK producer who is a medicines wholesaler or an importer must also—

(a) record the information mentioned in paragraph (4) for each presentation of imported special health service medicine which—

(i) the producer supplies to any relevant person, and

(ii) is, in the month in which the producer supplies it, listed in a Drug Tariff, and

(b) keep that information until it is provided to the Secretary of State in accordance with regulation 14.

(4) The information for a presentation is—

(a) the number of packs supplied to relevant persons, and

(b) the net sales income, or a reasonable estimate of the net sales income, for that supply.

(5) In this regulation, "relevant person"—

(a) in relation to a producer who is an importer, means—

(i) a UK primary medical services provider,

(ii) a Health Service chemist, or

(iii) a medicines wholesaler;

(b) in relation to a producer who is a medicines wholesaler, means—

(i) a UK primary medical services provider, or

(ii) a Health Service chemist.

Requirement to provide information about the supply of special health service medicines

14.—(1) A UK producer must provide the Secretary of State with the information which the producer is required to record and under regulation 11, 12, or 13 in accordance with this regulation.

(2) The information must be provided, in each year, for the following quarterly periods—

(a) 1st August to 31st October;

(b) 1st November to 31st January;

(c) 1st February to 30th April;

(d) 1st May to 31st July.

(3) The information for a quarterly period must be provided—

(a) in an electronic spreadsheet provided for that purpose by the Secretary of State, or

(b) if the Secretary of State does not provide such a spreadsheet, via the **[**[F18]NHS England**]** online gateway.

(4) The information for a quarterly period must be provided within the period of 28 days beginning with the first day of the month which begins immediately after the last day of that quarterly period.

F18 Words in reg. 14(3)(b) substituted (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(4)** (with reg. 3)

PART 4

General information about supply of UK health service products

Categories of purchaser

15. For the purposes of this Part—

(a) a person is in Category A if the person is a UK primary medical services provider or a Health Service chemist;

(b) a person is in Category B if the person is an NHS hospital purchaser or purchases UK health service products under an NHS framework contract**;**

(c) a person is in a Category C if the person—

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

(ii) is not in Category A or Category B;

(d) a person is in Category D if the person is not in any of Categories A to C.

Information to be recorded and kept about supply of imported special health service medicines: medicines wholesalers and importers

16.—(1) A UK producer who is a medicines wholesaler or an importer must—

(a) record the information mentioned in paragraph (2) for each purchase by the producer of a presentation of imported special health service medicine for supply, and

(b) keep that information for a period of four years beginning with the day on which it is recorded.

(2) The information is—

(a) the name of the person from whom the presentation is purchased,

(b) the quantity of packs purchased,

(c) the net purchase amount, or a reasonable estimate of the net purchase amount, for the purchase,

(d) the terms on which any discounts, payments, or payments or benefits in kind taken into account when calculating that amount were received, and

(e) the name of the person to whom the discounts, payments, or payments or benefits in kind were given, if that person is not the producer.

(3) A UK producer who is a medicines wholesaler or an importer must also—

(a) record the information mentioned in paragraph (4) for each supply of a presentation of imported special health service medicine by the producer, and

(b) keep that information for a period of four years beginning with the day on which it is recorded.

(4) The information is—

(a) the name of the person to whom the presentation is supplied (“the purchaser”),

(b) if known to the producer, whether the purchaser is in Category A, B, C or D,

(c) the quantity of packs supplied,

(d) the net sales income, or a reasonable estimate of the net sales income, for the supply,

(e) the terms on which the discounts, payments, or payments or benefits in kind taken into account when calculating that income were given by the producer,

(f) the name of the person to whom any of those discounts, payments, or payments or benefits in kind were given, if that person is not the purchaser, and

(g) if known to the producer**,** whether the presentation is an English health service product, a Welsh health service product, a Scottish health service product or a Northern Ireland health service product.

Information to be recorded and kept about supply of health service medicines other than imported special health service medicines: medicines wholesalers

17.—(1) A UK producer who is a medicines wholesaler must—

(a) record the information mentioned in paragraph (3) for each purchase by the producer of a relevant presentation of health service medicines for supply (including any purchase which requires the presentation to be imported into the United Kingdom), and

(b) keep that information for a period of four years beginning with the day on which it is recorded.

(2) The information is—

(a) the name of the person from whom the presentation is purchased,

(b) the quantity, by pack size, purchased,

(c) the net purchase amount, or a reasonable estimate of the net purchase amount, for the purchase,

(d) the terms on which the discounts, payments, or payments or benefits in kind taken into account when calculating that amount were given,

(e) the name of the person to whom the discounts, payments, payments or benefits in kind were given, if that person is not the wholesaler, and

(f) if it is a presentation of made special health service medicine, the excipient formulations purchased (if any).

(3) A UK producer who is a medicines wholesaler must also—

(a) record the information mentioned in paragraph (4) for each supply by the wholesaler of a relevant presentation of health service medicine, and

(b) keep that information for a period of four years beginning with the day on which it is recorded.

(4) The information is—

(a) the name of the person to whom the presentation is supplied (“the purchaser”),

(b) if known to the producer, whether the purchaser is in Category A, B, C or D,

(c) the quantity, by pack size, supplied,

(d) the net sales income, or a reasonable estimate of the net sales income, for the supply to the purchaser,

(e) the terms on which any discounts, payments, or payments or benefits in kind taken into account when calculating that income were given by the producer,

(f) the name of the person to whom any of those any discounts, payments, or payments or benefits in kind were given, if that person is not the purchaser,

(g) if it is a presentation of made special health service medicine, the excipient formulations supplied (if any), and

(h) if known to the producer, whether the presentation is an English health service product, a Welsh health service product, a Scottish health service product or a Northern Ireland health service product.

(5) In this regulation, "relevant presentation of health service medicine", in relation to a producer, means a presentation of health service medicine other than—

(a) a presentation which the producer has manufactured, or

(b) a presentation of imported special health service medicine.

Information to be recorded and kept about supply of health service medicines other than imported special health service medicines: other UK producers

18.—(1) A UK producer must—

(a) record the information mentioned in paragraph (2) for—

(i) each supply by the producer of a presentation of relevant health service medicine which the producer has manufactured, and

(ii) each supply by the producer (otherwise than as a medicines wholesaler) of any presentation of relevant health service medicine, and

(b) keep that information for a period of four years beginning with the day on which it is recorded.

(2) The information is—

(a) the name of the person to whom the presentation is supplied ("the purchaser"),

(b) if known to the producer, whether the purchaser is in Category A, B, C or D,

(c) the quantity, by pack size, supplied to the purchaser,

(d) the net sales income, or a reasonable estimate of the net sales income, for the supply of the presentation to the purchaser,

(e) the terms on which any discounts, payments, or payments or benefits in kind taken into account when calculating the net sales income were given by the producer,

(f) the name of the person to whom those discounts were given, if that person is not the purchaser,

(g) if known to the producer**,** whether the presentation is an English health service product, a Welsh health service product, a Scottish health service product or a Northern Ireland health service product, and

(h) if it is a presentation of made special health service medicine, the excipient formulations supplied (if any).

(3) In this regulation, "relevant health service medicine" means a health service medicine other than an imported special health service medicine.

Information to be recorded and kept about supply of health service medicines to patients otherwise than by sale

19.—(1) This regulation applies to a UK producer who supplies health service medicines to patients.

(2) A UK producer to whom this regulation applies must—

(a) record the information mentioned in paragraph (3) for each presentation of health service medicine which the producer purchases for the purpose of supply to patients, and

(b) keep that information for a period of four years beginning with the day on which it is recorded.

(3) The information is—

(a) the invoice for the purchase of the presentation,

(b) if any discounts, payments, payments or benefits in kind given in connection with the purchase are not included in the invoice, a statement of those discounts, payments or payments or benefits in kind,

(c) the name of the person from whom the presentation is purchased,

(d) the quantity, by pack size, purchased,

(e) the net purchase amount, or a reasonable estimate of the net purchase amount, paid for the purchase, and

(f) the terms on which any discounts, payments, or payments or benefits in kind were given to the producer.

(4) In this regulation, "supply" means supply otherwise than by sale.

Information to be recorded and kept about supply of health service appliances: manufacturers and importers

20.—(1) A UK producer must—

(a) record the information mentioned in paragraph (2) for each supply by the producer of any appliance—

(i) which the producer has manufactured or imported,

(ii) which is a UK health service product, and

(iii) which is, in the month in which the producer supplies it, listed in a Drug Tariff, and

(b) keep that information for a period of four years beginning with the day on which it is recorded.

(2) The information is—

(a) the name of the person to whom the appliance is supplied ("the purchaser"),

(b) if known to the producer, whether the purchaser is in Category A, B, C or D,

(c) the number of appliances supplied to the purchaser,

(d) the net sales income, or a reasonable estimate of the net sales income, from the supply,

(e) the terms on which any discounts, payments, or payments or benefits in kind taken into account when calculating that income were given by the producer,

(f) the name of any person to whom any discounts, payments, or payments or benefits in kind are given, if that person is not the purchaser, and

(g) if known to the producer**,** whether the appliance is an English health service product, a Welsh health service product, a Scottish health service product or a Northern Ireland health service product.

Information to be recorded and kept about supply of listed health service appliances: medical supplies wholesalers

21.—(1) A medical supplies wholesaler must—

(a) record the information mentioned in paragraph (2) for each purchase by the wholesaler of any appliance (including any purchase which requires the appliance to be imported into the United Kingdom) which—

(i) is a UK health service product, and

(ii) is, in the month in which the wholesaler purchases it, listed in a Drug Tariff, and

(b) keep that information for the period of four years beginning with the day on which it is recorded.

(2) The information is—

(a) the name of the person from whom the appliance is purchased,

(b) the number of appliances purchased,

(c) the net purchase amount, or a reasonable estimate of the net purchase amount, paid for the purchase,

(d) the terms on which any discounts, payments, or payments or benefits in kind taken into account when calculating that amount were given, and

(e) the name of the person to whom they are given, if the person to whom they are given is not the producer.

(3) A medical supplies wholesaler must also—

(a) record the information mentioned in paragraph (4) for each supply by the wholesaler of any appliance (other than an appliance which the wholesaler has manufactured or imported) which—

(i) is a UK health service product, and

(ii) is, in the month in which the wholesaler supplies it, listed in a Drug Tariff, and

(b) keep that information for the period of four years beginning with the day on which it is recorded.

(4) The information is—

(a) the name of the person to whom the appliance is supplied ("the purchaser"),

(b) if known to the producer, whether the purchaser is in Category A, B, C or D,

(c) the number of appliances supplied,

(d) the net sales income, or a reasonable estimate of the net sales income, from the supply,

(e) the terms on which any discounts, payments, or payments or benefits in kind taken into account when calculating that income were given,

(f) the name of any person to whom they were given if the person to whom they were given is not the purchaser, and

(g) if known to the wholesaler, whether the appliance is an English health service product, a Welsh health service product, a Scottish health service product or a Northern Ireland health service product.

Information to be recorded and kept about supply of appliances, food and dermatological products to patients otherwise than by sale

22.—(1) This regulation applies to any UK producer who supplies UK health service products which are not health service medicines to patients.

(2) A UK producer to whom this regulation applies must—

(a) record the information mentioned in paragraph (3) for each supply by the producer to patient otherwise than by sale of an appliance, food or dermatological product—

(i) which is a UK health service product, and

(ii) is, in the month in which the producer supplies it, listed in a Drug Tariff, and

(b) keep that information for a period of four years beginning with the day on which it is recorded.

(3) The information is—

(a) the invoice for the purchase of the appliance, food or dermatological product,

(b) if any discounts, payments or payments or benefits in kind given in connection with the purchase are not included in the invoice, a statement of those discounts, payments or payments or benefits in kind,

(c) the name of the person from whom the appliance, food or product is purchased,

(d) the number of appliances or quantity, by pack size, of product purchased,

(e) the net purchase amount, or a reasonable estimate of the net purchase amount, paid for the purchase,

(f) the terms on which any discounts, payments, or payments or benefits in kind taken into account when calculating that amount were given, and

(g) the name of the person to whom those discounts, payments or payments or benefits in kind were given, if that person is not the purchaser.

(4) For the purposes of paragraph (2), a food or dermatological product is listed in a Drug Tariff if the food or product is listed—

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

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

(c) in Part X of the Drug Tariff (Northern Ireland) for the given month.

(5) In this regulation "supply" means supply otherwise than by sale.

Provision of information recorded and kept under this Part to the Secretary of State

23.—(1) The Secretary of State may by request in writing require a UK producer to provide such of the retained information as the Secretary of State requires for the statutory purpose.

(2) A written request must state the statutory purpose for which the Secretary of State requires the information.

(3) A UK producer who is given a written request must comply with the request within the period of 28 days beginning with the day on which the producer is given the request.

(4) A producer must provide the requested information—

(a) in an electronic spreadsheet provided for that purpose by the Secretary of State, or

(b) if the Secretary of State does not provide such a spreadsheet, via the **[**F19NHS England**]** online gateway.

(5) In this regulation, "retained information", in relation to a UK producer, means the information which the producer is required to record and keep under this Part.

(6) This regulation is subject to regulation 24.

F19 Words in reg. 23(4)(b) substituted (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(5)** (with reg. 3)

Provision of information: small producers

24.—(1) A UK producer who is a small producer may provide information in response to a request under regulation 23 in the form of an invoice or other existing document.

(2) For the purposes of this regulation, whether a producer is a small producer is to be determined in accordance with Schedule 2.

(3) A producer to whom paragraph 6(1)(a) of Schedule 2 applies must, when responding to the relevant request under regulation 23, provide the Secretary of State with information, in writing, setting out the producer's net NHS sales income for the relevant financial year.

(4) The Secretary of State may, for the purposes of verifying any information provided under paragraph (3), request the producer who provided it to provide that information in audited form.

PART 5

Information about costs incurred in connection with the manufacturing, distribution or supply of UK health service products

Provision of information about costs incurred in connection with the manufacture or distribution of a particular health service medicine or appliance

25.—(1) If the Secretary of State requires the information for the statutory purpose, the Secretary of State may by information notice [F20] require a UK producer to provide specified information in respect of any relevant costs incurred by the producer—

(a) in connection with the manufacturing of a particular presentation of unbranded generic health service medicine or special health service medicine;

(b) in connection with the distribution or supply of a particular presentation of health service medicine;

(c) in connection with the manufacturing, supply or distribution of a particular appliance which—

(i) is a UK health service product, and

(ii) is, in the month in which the request is made, listed in a Drug Tariff.

(2) But the Secretary of State may not require a UK producer to provide any information which the producer could not reasonably be expected to record and keep for the purpose of understanding the producer's relevant costs.

(3) An information notice must specify the statutory purpose for which the specified information is required.

(4) A UK producer must comply with any information notice given to the producer.

(5) In this regulation—

"relevant costs", in relation to a producer, means any costs (including, for example, manufacturing costs, supply costs, distribution costs, research and development cost, capital costs and business costs) other than costs which relate to any transaction between the producer and a UK producer for the relevant health service product;

"specified" means specified in an information notice.

F20 See the definition of "information notice" in section 264A(6) of the National Health Service Act 2006.

Provision of general information about costs incurred in connection with the manufacture or distribution of health service medicines and appliances

26.—(1) If the Secretary of State requires the information for the statutory purpose, the Secretary of State may by request, in writing, require a UK producer—

(a) to provide information about any costs incurred by the producer—

(i) in connection with the manufacturing or distribution of a particular presentation of health service medicine, and

(ii) which relate to any transaction between the producer and a UK producer for that presentation;

(b) to provide information about any costs incurred by the producer—

(i) in connection with the manufacturing or distribution of a particular appliance which—

(aa) is a UK health service product, and

(bb) is, in the month in which the request is made, listed in a Drug Tariff, and

(ii) which relate to any transaction between the producer and a UK producer for that appliance;

(c) to provide information about any costs (other than supply costs) incurred by the producer in connection with the manufacturing, or distribution of—

(i) any health service medicine, or

(ii) any appliance which is—

(aa) a UK health service product, and

(bb) in the month in which the request is made, listed in a Drug Tariff.

(2) But a request under paragraph (1)(a), (b) or (c) may not require a UK producer to provide any information which the producer could not reasonably be expected to record and keep for the purpose of understanding the producer's relevant costs.

(3) In addition, a request under paragraph (1)(c) may not require a UK producer to provide any information to which regulation 25 applies.

(4) A UK producer who is given a written request under paragraph (1)(a), (b) or (c) must comply with the request.

(5) The producer must provide the requested information—

(a) in an electronic spreadsheet provided for that purpose by the Secretary of State, or

(b) if the Secretary of State does not provide such a spreadsheet, via the **[**F21NHS England**]** online gateway.

(6) The producer must provide the requested information within the period of 28 days beginning with the day on which the producer is given the request.

F21 Words in reg. 26(5)(b) substituted (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(6)** (with reg. 3)

PART 6

Information about price and availability of health service medicines

Provision of information about English health service medicines which are not available at the reimbursement price

27.—(1) This regulation applies where the Secretary of State has reasonable grounds to suspect that a presentation of English health service medicine is, in a particular month, available for distribution or supply to English NHS chemists at a price which exceeds the listed price.

(2) Where this regulation applies, the Secretary of State may, by request in writing, require any of the following UK producers to provide the information mentioned in paragraph (3) for the relevant presentation—

(a) a manufacturer of the presentation,

(b) a person who distributes the presentation (whether by wholesale dealing or otherwise), or

(c) an importer of the presentation.

(3) The information is—

(a) the quantity, by relevant pack size, of the presentation which is available for distribution or supply by the producer in England,

(b) the net price or net prices, or a reasonable estimate of the net price or net prices, at which the producer would offer to distribute or supply those pack sizes in England,

(c) the quantity, by relevant pack size, of any branded equivalent which is available for distribution or supply by the producer in England, and

(d) the net price or net prices, or a reasonable estimate of the net price or net prices, at which the producer would offer to distribute or supply those pack sizes in England.

(4) A producer who is given a written request under paragraph (2), must comply with the request within the period of two working days beginning—

(a) with the day on which producer is given the request, if that day is a working day;

(b) otherwise, with the first working day after the day on which the notice is given to the producer.

(5) In this regulation—

"branded equivalent", in relation to a presentation of English health service medicine, means a particular form of medicinal product—

(a) to which a brand name has been applied that enables the medicine to be identified without reference to the common name, but

(b) which has the same—

(i) active ingredient or ingredients,

(ii) strength,

(iii) physical form,

(iv) unit dose (if applicable),

(v) method of administration (if applicable),

(vi) freeness (if applicable), and

(vii) type of packaging,

as the presentation;

"English health service medicine" means a medicinal product used to any extent for the purposes of the health service continued under section 1(1) of the 2006 Act;

"listed price", in relation to a presentation of English health service medicine, means the price listed for that medicine in Part VIII of the Drug Tariff (England);

"net price", in relation to a presentation, means the price after the deduction of—

(a) all discounts and payments, and

(b) the value of all payments or benefits in kind;

"relevant pack size"—

(a) in relation to a presentation of English health service medicine which—

(i) is a presentation of unbranded generic health service medicine, and

(ii) is a liquid or a topical preparation or is in tablet or capsule form,

means any pack size which does not exceed the maximum pack size;

(b) in relation to any other presentation of English health service medicine or a branded equivalent, means any pack size.

(6) For the purposes of this regulation—

(a) the definition of "presentation" in paragraph 2 of Schedule 1 applies as if any reference to pack size were omitted, and

(b) for the purpose of determining whether there is price listed in Part VIII of the Drug Tariff (England), any pack size specified in that Part is to be disregarded.

Provision of information about availability of health service medicines

28.—(1) This regulation applies where the Secretary of State considers that there is a supply shortage of a presentation of health service medicine (the "relevant presentation").

(2) Where this regulation applies, the Secretary of State may by notice in writing require any of the following to provide the information mentioned in paragraph (3) about the relevant presentation—

(a) a manufacturer of the presentation,

(b) a person who distributes the presentation (whether by wholesale dealing or otherwise), or

(c) an importer of the presentation.

(3) The information is—

(a) the quantity (if any) of packs of the relevant presentation that is available for supply by the producer, and

(b) the quantity (if any) of any alternative presentation specified in the request that is available for supply by the producer.

(4) A producer who is given a notice under paragraph (2) must comply with the request within the period of two working days beginning—

(a) with the day on which producer is given the request, if that day is a working day;

(b) otherwise, with the first working day after the day on which the notice is given to the producer.

(5) In this regulation, "alternative presentation", in relation to a relevant presentation, means a presentation of health service medicine which is used as a therapeutic alternative to the relevant presentation.

Requirement to provide information about discontinuation or anticipated supply shortage of certain health service medicines

29.—(1) This regulation applies where a designated producer of a notifiable presentation—

(a) intends to discontinue the manufacturing or supply of the presentation and considers that this is likely to have a direct impact on any patient who takes, or may need to take, the presentation for the prevention or treatment of a physical or mental illness, or

(b) considers there is likely to be a supply shortage of the presentation which will have a direct impact on any patient who takes, or may need to take, the presentation for the prevention or treatment of a physical or mental illness.

(2) Where this regulation applies, the designated producer must provide the following information to the Secretary of State—

(a) the name of the presentation,

(b) the licensed uses of the presentation which the producer is aware of,

(c) the unlicensed uses of the presentation which the producer is aware of,

(d) the reasons for which the manufacturing or supply is to be discontinued or, as the case may be, the producer considers there is likely to be a supply shortage,

(e) the quantity of the presentation which the producer has available for supply,

(f) where the producer considers there is likely to be a supply shortage—

(i) the anticipated duration of the shortage;

(ii) any steps taken by the producer to address it,

(g) the producer's estimated share of the market,

(h) whether the presentation is made available under an NHS framework contract, and

(i) the name and contact details of a representative of the producer.

(3) The information must be provided—

(a) where the producer intends to discontinue the manufacturing or supply of the relevant presentation—

(i) at least six months before the day on which the manufacturing or supply will cease, or

(ii) where the decision to discontinue the manufacturing or supply is made less than six months before the day on which manufacturing or supply will cease, as soon as reasonably practicable after the producer makes the decision;

(b) where the producer considers there may be a supply shortage of the relevant presentation—

(i) at least six months before any anticipated impact on any patient who takes the presentation is realised, or

(ii) where the producer becomes aware of the likely supply shortage less than six months before the producer considers any anticipated impact will be realised, as soon as reasonably practicable after the producer becomes aware that there may be a supply shortage.

(4) In this regulation—

"notifiable presentation" means a presentation of health service medicine in respect of which a **[**F22UK**]** marketing authorisation has been granted F23...

"designated producer", in relation to a notifiable presentation, means—

(a) the UK producer who holds the **[**F24UK**]** marketing authorisation for the presentation, if that producer manufactures the presentation;

(b) otherwise, a UK producer who manufactures the presentation or imports the presentation and supplies it by way of sale;

"**[**[F25]UK**]** marketing authorisation" has the meaning given in regulation 8(1) of the 2012 Regulations.

F22 Word in reg. 29(4) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 8 para. 15(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
F23 Words in reg. 29(4) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 8 para. 15(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
F24 Word in reg. 29(4) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 8 para. 15(b)**; 2020 c. 1, Sch. 5 para. 1(1)
F25 Word in reg. 29(4) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 8 para. 15(c)**; 2020 c. 1, Sch. 5 para. 1(1)

PART 7

Information about reasonable estimates

Requirement to provide information about reasonable estimates

30.—(1) This regulation applies if a UK producer provides any information to the Secretary of State under or in accordance with these Regulations in the form, or on the basis, of a reasonable estimate.

(2) Where this regulation applies, the Secretary of State may by request in writing require the producer to provide the following information to the Secretary of State—

(a) the reasons for which the producer provided the original information in the form, or on the basis, of a reasonable estimate, rather than an actual amount, and

(b) the method used by the producer to calculate the reasonable estimate.

(3) A UK producer who is given a request under paragraph (2) must comply with the request within the period of seven days beginning with the day on which the producer is given the request.

PART 8

Enforcement and appeals

Compliance procedure

31.—(1) If the Secretary of State considers that a UK producer—

(a) has not complied with regulation 9, 14 or 29,

(b) has provided information under regulation 9, 14 or 29 which is incorrect or incomplete,

(c) has not complied with a written request given to the producer under regulation 23, 24, 26, 27, 28 or 30 ("the original request"), or

(d) has provided information in response to an original request which is incorrect or incomplete,

the Secretary of State may by notice in writing require the producer to provide any of the relevant information or to provide relevant information which is accurate. Such a notice is referred to in these Regulations as a "compliance notice".

(2) A compliance notice must—

(a) specify the provision of these Regulations or the original request to which the notice relates,

(b) specify the relevant information to be provided to the Secretary of State,

(c) state the additional compliance period within which that information is to be provided,

(d) state that the Secretary of State may demand a penalty from the producer if the information is not provided within that period, and

(e) state that there is a right of appeal against the compliance notice in accordance with the 2000 Regulations.

(3) For the purposes of paragraph (2), "additional compliance period"—

(a) in relation to a compliance notice which relates to regulation 9, 14 or 29, means the period of seven working days beginning—

(i) with the day on which the compliance notice is given to the producer, if that day is a working day;

(ii) otherwise, with the first working day after the day on which the compliance notice is given to the producer;

(b) in relation to a compliance notice which relates to an original request made under regulation 27 or 28, means the period of one working day beginning—

(i) with the day on which the compliance notice is given to producer, if that day is a working day;

(ii) otherwise, with the first working day after the day on which it is given to the producer;

(c) in any other case, means the period of 30 working days beginning—

(i) with the day on which it is given to the producer, if that day is a working day;

(ii) otherwise, with the first working day after the day on which it is given to the producer.

(4) But where the original request was made under regulation 23, the Secretary of State may, instead of the period mentioned in paragraph (3)(c), specify an additional compliance period of seven working days beginning—

(a) with the day on which it is given to the producer, if that day is a working day, or

(b) otherwise, with the first working day after the day on which it is given to the producer.

(5) A UK producer who is given a compliance notice must comply with that notice.

(6) If a UK producer—

(a) is given a compliance notice in relation to an original request, and

(b) the producer is a small producer in connection with that request,

the producer may provide any or all of the required information specified in the notice in the form of an invoice or other existing document.

(7) For the purposes of paragraph (6), whether a UK producer is a small producer is to be determined in accordance with Schedule 2.

(8) In this regulation, "relevant information", in relation to a producer, means any of the information—

(a) the producer is required to provide to the Secretary of State under regulation 9, 14 or 29, or

(b) specified in the original request.

Penalties

32.—(1) This regulation applies where a UK producer contravenes regulation 25(4) or 31(5).

(2) Where this regulation applies—

(a) the producer is liable to pay a penalty to the Secretary of State, and

(b) the amount of the penalty is to be determined in accordance with paragraphs (3) and (4).

(3) If the producer contravenes regulation 31(5) by failing to comply with a compliance notice relating to regulation 27 or 28, the amount of the penalty is a single penalty of £1,000.

(4) If the producer contravenes regulation 25(4), or contravenes regulation 31(5) by failing to comply with any other compliance notice, the amount of the penalty is a daily penalty and is to be calculated—

(a) if the producer is a small producer, in accordance with paragraph 2 of Schedule 3;

(b) in the case of any other producer, in accordance with paragraph 3 of Schedule 3.

But this paragraph is subject to paragraphs (9) and (10).

(5) Whether a UK producer is a small producer is to be determined in accordance with Schedule 2.

(6) Where a producer is liable to pay a penalty under this regulation, the Secretary of State may by demand in writing require the producer to pay that penalty to the Secretary of State.

(7) A written demand under paragraph (6) must—

(a) specify—

(i) if the penalty payable by the producer is a single penalty, that the amount of the penalty is £1,000;

(ii) if the penalty payable by the producer is a daily penalty, the information mentioned in paragraph (8);

(b) give the Secretary of State's reasons for imposing the penalty;

(c) specify the period within which the penalty is to be paid;

(d) state that the decision to require the producer to pay the penalty, and the decision as to the amount of the penalty, may be appealed under the 2000 Regulations.

(8) The information is—

(a) the date on which the contravention occurred,

(b) the amount of the daily penalty calculated in accordance with this regulation and Schedule 3 from that day up to and including the day on which the demand is made, and

(c) the daily rate at which the penalty continues to accrue in accordance with Schedule 3 until the producer complies with the relevant information notice or compliance notice (except to the extent that it is no longer to possible to meet a deadline because the deadline has passed).

(9) For the purposes of calculating the final amount of the daily penalty that is due, the day on which the producer starts to comply with the relevant notice is to be disregarded.

(10) If the producer makes an appeal to the tribunal against the decision under this regulation to require the producer to pay a daily penalty, or as to the amount of that daily penalty, in accordance with regulation 4 of the 2000 Regulations, any day falling within the appeal period is to be disregarded when determining the final amount of the penalty to be paid by the producer.

(11) For the purposes of paragraph (10), "appeal period" means the period—

(a) beginning with the day on which the tribunal receives the relevant notice of appeal, and

(b) ending with—

(i) the day on which the appeal is withdrawn, or

(ii) if the decision is upheld following the appeal, the day on which the appeal is finally determined.

Appeals

33.—(1) A UK producer has a right of appeal against a relevant enforcement decision in accordance with the 2000 Regulations.

(2) For this purpose, the 2000 Regulations apply in relation to relevant enforcement decisions as they apply to enforcement decisions (within the meaning of those Regulations) but with the modification specified in paragraph (3).

(3) The modification is that a reference to an enforcement decision is to be read as a reference to a relevant enforcement decision (within the meaning of this regulation).

(4) In this regulation "relevant enforcement decision", in relation to a producer, means a decision of the Secretary of State—

(a) to give the producer an information notice under regulation 25,

(b) to give the producer a compliance notice,

(c) to require the producer to pay a penalty under regulation 32, or

(d) as to the amount of such a penalty.

PART 9

Disclosure of information

Disclosure of information

34. Schedule 4—

(a) prescribes bodies for the purposes of sections 264B(1)(k) and (l) of the 2006 Act, and

(b) prescribes the purposes for which those bodies may use information disclosed under section 246B(1) of the 2006 Act.

PART 10

Miscellaneous

Transitional provisions

35.—(1) Until the coming into force of the repeal of section 27 of the 1978 Act by Schedule 3 to the Smoking, Health and Social Care (Scotland) Act 2005 [F26], any reference in these Regulations to pharmaceutical care services under section 2CA(1) of the 1978 Act is to be read as a reference to pharmaceutical services under section 27(1) of that Act.

(2) Schedule 5 makes transitional provision—

(a) in respect of the recording, keeping and provision of information about the supply of unbranded generic health service medicines by UK producers who are members of Scheme M or Scheme W, and

(b) in respect of the recording, keeping and provision of information about the supply of special health service medicines by UK producers who are participating manufacturers for the purposes of the Specials MoU.

(3) In this regulation—

"Scheme M" means the Scheme made by the Secretary of State and the British Generic Manufacturers Association which is dated March 2010 and known as the "Revised long-term arrangements for reimbursement of generic medicines (Scheme M)"[F27];

"Scheme W" means the Scheme made by the Secretary of State, the British Association of Pharmaceutical Wholesalers and the British Association of Generic Distributors which is dated June 2005 and known as the "New long-term arrangements for reimbursement of generic medicines (Scheme W)"[F28];

"Specials MoU" means the Memorandum of Understanding agreed by the Secretary of State and the Association of Commercial Specials Manufacturers for the purpose of the provision of information to inform Drug Tariff specials reimbursement prices.

F26 2005 asp 13.

F27 Scheme M is available from the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU or online at: http://webarchive.nationalarchives.gov.uk/20130123201658/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_115260
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F28 Scheme W is available from the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU or online at: http://webarchive.nationalarchives.gov.uk/20130123204650/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4114370

Annual review

36.—(1) The Secretary of State must from time to time—

(a) carry out a review of the regulatory provisions contained in these Regulations,

(b) set out the conclusions of the review in a report, and

(c) publish the report.

(2) The first report under these Regulations must be published before 1st July 2019.

(3) Subsequent reports must be published at intervals not exceeding one year.

(4) A report published under this regulation must, in particular—

(a) set out the objectives intended to be achieved by the regulatory provisions contained in these Regulations,

(b) assess the extent to which those objectives are achieved,

(c) assess whether those objectives remain appropriate, and

(d) if those objectives remain appropriate, assess the extent to which they could be achieved in another way which involves less onerous regulatory provisions.

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

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

SCHEDULE 1 Regulation 2

Interpretation: general

Interpretation: general

1.—(1) In these Regulations—

"the 1978 Act" means the National Health Service (Scotland) Act 1978 [F29];

"the 2006 Act" means the National Health Service Act 2006 [F30];

"the 2006 Wales Act" means the National Health Service (Wales) Act 2006 [F31];

"the 1972 Order" means the Health and Personal Social Services (Northern Ireland) Order 1972 [F32];

"the 2000 Regulations" means the Health Service Medicines (Price Control Appeals) Regulations 2000 [F33];

"the 2012 Regulations" means the Human Medicines Regulations 2012 [F34];

"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 [F35];

"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 [F36];

"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 [F37];

"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 [F38];

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

[F39]...

"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);

[F39]...

[[F40]"NHS England" means the body corporate established under section 1H of the National Health Service Act 2006;**]**

[[F40]"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 [F41] or in Part 4 of Schedule 1 to the Freedom of Information (Scotland) Act 2002 [F42]; 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 [F43].

(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.**]**

F29 1978 c.29.
F30 2006 c. 41.
F31 2006 c. 42.
F32 S.I. 1972/1265 (N.I. 14).
F33 S.I. 2000/124, amended by S.I. 2000/870, 2006/860, 2007/1898 and 2018/384.
F34 S.I. 2012/1916, amended by S.I. 2013/1855, 2016/186 and 2017/715; there are other amending instruments but none is relevant.
F35 S.I. 2013/349, to which there are amendments not relevant to these Regulations.
F36 S.R. 1997 No.381.
F37 S.I. 2013/898 (W. 102), to which there are amendments not relevant to these Regulations.
F38 2006 c. 46.
F39 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)
F40 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)
F41 2000 c. 36.
F42 2002 asp 13.

F43 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 [F44];

"the 2012 Scotland Regulations" means the Public Contracts (Scotland) Regulations 2012 [F45];

"the 2015 Regulations" means the Public Contracts Regulations 2015 [F46];

"the 2015 Scotland Regulations" means the Public Contracts (Scotland) Regulations 2015 [F47];

"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.

F44 S.I. 2006/5; the Regulations were revoked, subject to transitional provisions, by the Public Contracts Regulations 2015 (S.I. 2015/102), **regulation 116**.
F45 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.
F46 S.I. 2015/102, to which there are amendments not relevant to these Regulations.
F47 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 **[**F48integrated 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 F49	The purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(k).

F48 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))

F49 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.

EXPLANATORY NOTE

(This note is not part of the Regulations)

Section 264A of the National Health Service Act 2006 ("the 2006 Act") provides for the Secretary of State to make regulations to require UK producers to record and keep information which the Secretary of State may require for the purpose set out in subsection (3) of that section and to provide that information to Secretary of State (section 264A(2) of the 2006 Act).

A "UK producer" is a person who manufactures, distributes or supplies any UK health service products (section 264A(1) of the 2006 Act). "UK health service products" are medicinal products, medical supplies and other related products used for any purposes of any of the health services in England, Wales, Scotland or Northern Ireland (section 264A(10) to (15)).

Section 264B of the 2006 Act sets out the persons to whom information provided by virtue of section 264A may be disclosed. That section imposes further restrictions on the use of any such information which is commercially sensitive or confidential. The persons to whom information may be disclosed include persons prescribed in regulations by the Secretary of State under section 264B(1)(k) or (l). The Secretary of State must also prescribe in regulations the purposes for which those bodies may use any commercially sensitive or confidential information.

These Regulations make provision for the purposes of sections 264A and 264B(1)(k) and (l) of the 2006 Act.

Part 1 of the Regulations

Part 1 of the Regulations deals with citation and commencement of the Regulations (regulation 1), their application (regulation 3), exceptions (regulation 4) and presumptions which will apply if information is provided to the Secretary of State via an online gateway.

Regulation 2 and Schedule 1 are the general interpretation provisions for the Regulations. The terms defined here include "primary medical services provider", "NHS chemist", "importer", "wholesaler" and "presentation of health service medicine".

Part 2 of the Regulations

Part 2 of the Regulations deals with routine provision of information about the supply of unbranded generic health service medicines. "Unbranded generic health service medicine" is defined in regulation 6.
Manufacturers and importers of unbranded generic health service medicines must record and keep information about supplies of unbranded generic health service medicines in accordance with regulation 7. Wholesalers must record and keep information about their purchases and supply of unbranded generic health service medicines in accordance with regulation 8.
That information must be provided to the Secretary of State at quarterly intervals (regulation 9).

Part 3 of the Regulations

Part 3 of the Regulations deals with routine provision of information about the supply of made and imported special health service medicines. "Made special health service medicine" and "imported special health service medicine" are defined in regulation 10.
Manufacturers of made special health service medicines must record and keep information about their supply of those medicines in accordance with regulation 11. Wholesalers must record and keep information about their purchases and supply of made special health service medicines in accordance with regulation 12. Wholesalers and importers must record and keep information about their purchases and supply of imported special health service medicines in accordance with regulation 13.
That information must be provided to the Secretary of State at quarterly intervals (regulation 14).

Part 4 of the Regulations

Part 4 of the Regulations deals with the provision on request of general information about the supply of UK health service products. The key terms used in this Part are defined in regulation 15.
Regulations 16 to 19 set out the information about the supply of health service medicines that is to be recorded and kept by UK producers.
Regulations 20 to 22 set out the information out the information that is to be recorded and kept by UK producers about the supply of certain appliances and borderline substances.
The Secretary of State may, by written request, require a UK producer to provide any of the information recorded and kept under any of regulations 16 to 22 (regulation 23).
A UK producer who is a small producer may provide any of the requested information in the form of existing documents such as invoices (regulation 24). Whether a UK producer is a small producer is determined in accordance with Schedule 2 to the Regulations.

Part 5 of the Regulations

Part 5 of the Regulations deals with the provision of information about costs incurred by UK producers in connection with the manufacturing, distribution or supply of UK health service products.
The Secretary of State may, by information notice, require a producer to provide information about costs incurred in:

(a) the manufacturing of a particular presentation of unbranded generic health service medicine or special health service medicine,

(b) the distribution or supply of a particular presentation of health service medicine, or

(c) the manufacturing, distribution or supply of a particular appliance.
(regulation 25).
"Information notice" is defined in section 264A(6) of the 2006 Act. A producer who receives an information notice under this regulation may appeal that notice (regulation 33).
The Secretary of State may, by request in writing, require that a producer provide information about costs other than those mentioned above in accordance with regulation 26.

Part 6 of the Regulations

Part 6 of the Regulations deals with the provision of information about the price and availability of health service medicines.
Where the Secretary of State has reasonable grounds to suspect that a medicine is not available for supply to NHS chemists in England at the listed price, the Secretary of State may require manufacturers, importers or wholesalers of the medicine to provide information about the quantity available for supply in England and related prices. "The listed price" is the price listed for the medicine in Part VIII of the Drug Tariff (England) (regulation 27).
The Secretary of State may also require UK producers to provide information where the Secretary of State considers that there is a supply shortage of particular medicine (regulation 28).
Manufacturers and importers of health service medicines (other than medicines which are parallel imported or distributed) must notify the Secretary of State if:

(a) they intend to stop manufacturing or supplying a medicine and they consider this could have an impact on patients, or

(b) they consider there is likely to be a supply shortage of a medicine which could have an impact on patients.

(regulation 29).

Part 7 of the Regulations

Information that UK producers are required to provide under the Regulations may, in certain cases, be provided in the form of a reasonable estimate, rather than an actual amount. Where a producer provides information on the basis of such an estimate, regulation 30 allows the Secretary of State to require the producer to explain why an estimate has been used and also the method used to calculate that estimate.

Part 8 of the Regulations

Part 8 of the Regulations deals with enforcement and appeals.
If a UK producer does not comply with an obligation to provide information in or under the Regulations, or provides information which is incorrect or incomplete, the Secretary of State may give the producer a compliance notice (regulation 31). The notice must state the obligation that the Secretary of State considers the producer has not complied with, the information to be provided to remedy the failure and the period within which that information must be provided.
A UK producer who is given a compliance notice has a right of appeal against that notice (regulation 33).
If a UK producer does not comply with an information notice or a compliance notice, the producer becomes liable to pay a penalty to the Secretary of State (regulation 32). The amount of the penalty is to be calculated in accordance with regulation 32 and Schedule 3. There are different levels of penalty for UK producers who are small producers and those who are not. Whether a producer is a small producer is to be determined in accordance with Schedule 2.
The Secretary of State may issue a demand to a producer who is liable to pay a penalty requiring the payment of that penalty. A UK producer who is given such a demand has a right of appeal against the decision to require the payment of the penalty and also the amount of the penalty

(regulation 33(6)). No daily penalty is payable for any day falling during the period for which the appeal is ongoing (regulation 32(10)).

Part 9 of the Regulations

Regulation 34 and Schedule 4 prescribe bodies for the purposes of section 264B(1)(k) and (l) of the 2006 Act. Those provisions also prescribe, in accordance with section 264B(3)(g) of the 2006 Act, the purpose for which those bodies may use any confidential or commercially sensitive information disclosed to them under section 264B of the 2006 Act.

Part 10 of the Regulations

Regulation 35 and Schedule 5 make transitional provision.
Regulation 36 provides for an annual review of the operation of the Regulations. The report setting out the first review of the Regulations must be published by 1st July 2019.
An impact assessment relating to these Regulations has been prepared and copies can be obtained from the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU.

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