
STATUTORY INSTRUMENTS

[2017][2018] No. 000

**NATIONAL HEALTH SERVICE, ENGLAND AND
WALES**

NATIONAL HEALTH SERVICE, SCOTLAND

HEALTH AND SOCIAL CARE, NORTHERN IRELAND

**The Health Service Products (Provision of Information and
Disclosure) Regulations [2017] [2018]**

<i>Made</i>	- - - -	* * *
<i>Laid before Parliament</i>		* * *
<i>Coming into force</i>	- -	* * *

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SCHEDULE

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

The Secretary of State has consulted in accordance with sections 264C(1) and 265(9) of the National Health Service Act 2006(b).

Citation and commencement

1. These Regulations may be cited as the Health Service Products (Provision of Information and Disclosure) Regulations [2017] [2018] and come into force on [date].

Interpretation

2.—(1) In these Regulations—

“the 1978 Act” means the National Health Service (Scotland) Act 1978(c);

“the 2000 Act” means the Freedom of Information Act 2000(d);

“the 2002 Act” means Freedom of Information (Scotland) Act 2002(e);

“the 2006 Act” means the National Health Service Act 2006;

“the 2009 Act” means the Health and Social Care (Reform) Act (Northern Ireland) 2009(f);

“the 2012 Regulations” means the Human Medicines Regulations 2012(g);

“the 2013 Regulations” means the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(h);

“authorised health service medicine” means a health service medicine in respect of which a marketing authorisation, within the meaning of regulation 8(1) of the 2012 Regulations(i), has been granted or renewed;

“Drug Tariff”, unless the context otherwise requires, is the publication known as the Drug Tariff, published by the Secretary of State under regulation 89 of the 2013 Regulations;

“health service use” means—

(a) as regards medicinal products, use to any extent for the purposes of—

(i) the health service continued under section 1(1) of the 2006 Act,

(ii) health care provided by virtue of the 2009 Act,

(iii) the health service within the meaning of the 1978 Act, or

(iv) the health service continued under section 1(1) of the National Health Service (Wales) Act 2006(j); or

(b) as regards any other medical supplies or other related products, use as a consequence of being required for the purposes of—

(i) the health service continued under section 1(1) of the 2006 Act,

(ii) health care provided by virtue of the 2009 Act,

(a) 2006 c. 41. Sections 264A and 264B were inserted into the National Health Service Act 2006 (“the 2006 Act”) by the Health Service Medical Supplies (Costs) Act 2017 (c. 23) (“the 2017 Act”), section 8. Section 265(5)(b) and (5A) of the 2006 Act were inserted by the 2017 Act, section 10(9) and (10).

(b) Section 264C was inserted into the 2006 Act by the 2017 Act, section 8; and section 265(9) was inserted by the 2017 Act, section 10(13).

(c) 1978 c. 29.

(d) 2000 c. 36.

(e) asp 13.

(f) 2009 c. 1.

(g) S.I. 2012/1916.

(h) S.I. 2013/349.

(i) There are no relevant amending instruments.

(j) 2006 c. 42.

- (iii) the health service within the meaning of the 1978 Act, or
- (iv) the health service continued under section 1(1) of the National Health Service (Wales) Act 2006;

“NHS chemist” means any person who—

- (a) provides pharmaceutical or local pharmaceutical services under Part 7 of the 2006 Act or as mentioned in section 264A(9) of that Act(a); and
- (b) is not also a primary medical services provider;

“NHS framework agreement” means a framework agreement concluded under—

- (a) Part 3 of the Public Contracts Regulations 2006(b) or Part 2 of the Public Contracts Regulations 2015(c) in respect of the purchase of UK health service products by a body mentioned in Part 3 of Schedule 1 to the 2000 Act; or
- (b) Part 3 of the Public Contracts (Scotland) Regulations 2012(d) or Chapter 2 of the Public Contracts (Scotland) Regulations 2015(e) in respect of the purchase of UK health service products by a body mentioned in Part 4 of Schedule 1 to the 2002 Act;

“NHS prescription” means any prescription that could be dispensed by an NHS chemist under the 2013 Regulations or under equivalent arrangements in Wales, Scotland or Northern Ireland;

“payments” includes payments in kind;

“presentation” means a particular form of health service medicine which may be distinguished from other forms of the medicine by reference to its active ingredients, strength and excipients, pack size, type of packaging, method of administration or formulation;

“primary medical services provider” means any person who provides primary medical services (who may be a provider of pharmaceutical services as well as primary medical services) under—

- (a) Part 4 of the 2006 Act;
- (b) Part 4 of the National Health Service (Wales) Act 2006;
- (c) section 2C of the 1978 Act(f), a contract under section 17J of the 1978 Act(g) or an agreement under section 17C of the 1978 Act(h); or
- (d) Part 2 or 6 of the Health and Personal Social Services (Northern Ireland) Order 1972(i);

“relevant UK producer” means any UK producer apart from—

- (a) a primary medical services provider in Wales, Scotland or Northern Ireland; or
- (b) an NHS chemist in Wales, Scotland or Northern Ireland;

“small UK producer” means a UK producer that is not a primary medical services provider but with a total annual United Kingdom turnover of £5 million or less, as set out in their most recent submitted accounts;

“submitted accounts” means annual accounts filed at Companies House pursuant to the Companies Act 2006(a);

(a) See also section 264A(16), which contains a transitional provision which applies until the coming into force of the repeal of section 27 of the National Health Service (Scotland) Act 1978 by Schedule 3 of the Smoking, Health and Social Care (Scotland) Act 2005 and which relates to the provision of pharmaceutical services in Scotland.

(b) S.I. 2006/5; revoked together with the amendments to it by S.I. 2015/102.

(c) S.I. 2015/102.

(d) SSI 2015/88; revoked together with the amendments to it by SSI 2015/446.

(e) SSI 2015/446.

(f) Section 2C was inserted by the Primary Medical Services (Scotland) Act 2004 (asp 1), section 1(2), and has been amended by: the National Health Service Reform (Scotland) Act 2004 (asp 7), Schedule 1, paragraph 1(3); the Tobacco and Primary Medical Services (Scotland) Act 2010 (asp 3), section 37; and SSI 2010/283.

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

(h) Section 17C was inserted by the National Health Service (Primary Care) Act 1997 (c. 46), section 21(2), and has been amended by: the Primary Medical Services (Scotland) Act 2004, section 2(2); and the Health and Social Care Act 2012 (c. 7), Schedule 21, paragraph 3(2)(a).

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

“UK health service hospital” means a body which —

- (a) is mentioned in Part 3 of Schedule 1 to the 2000 Act and is responsible, under the arrangements for managing a hospital that supplies UK health service products to patients, for purchasing those health service products; or
- (b) is mentioned in Part 4 of Schedule 1 to the 2002 Act and is responsible, under the arrangements for managing a hospital that supplies UK health service products to patients, for purchasing those health service products;

“wholesale dealer” means—

- (a) a holder of a wholesale dealer’s licence, as referred to in regulation 18 of the 2012 Regulations; or
- (b) a person who distributes by way of wholesale dealing UK health service products that are not health service medicines.

(2) In these Regulations, the category of purchaser is to be identified by reference to one of the following—

- (a) Category A if the purchaser is a primary medical services provider or an NHS chemist;
- (b) Category B if the purchaser is a UK health service hospital or a purchaser (not being a UK health service hospital) under an NHS framework agreement;
- (c) Category C, if the purchaser is a wholesale dealer, but—
 - (i) the purchaser is not also a primary medical services provider, an NHS chemist or a UK health service hospital, or
 - (ii) the product is not purchased under an NHS framework agreement;
- (d) Category D in all other cases.

(3) Where reference is made in these Regulations, in whatever form, to a UK producer being a person who manufactures, distributes or supplies a UK health service product, the related requirements only apply to that producer if the producer knows, or it is obvious to a reasonable person in the circumstances that—

- (a) the product is to be; or
- (b) some or all of the products that the producer manufactures, distributes or supplies of that presentation (in the case of medicines) or particular description (in the case of foods, dermatological products or appliances) are to be,

for health service use.

Quarterly provision of information about unbranded generic health service medicines and special medicinal products

3.—(1) A UK producer that—

- (a) manufactures or distributes health service medicines; or
- (b) not being the manufacturer or distributor of health service medicines, is an importer of health service medicines who supplies those medicines,

must record and keep the information mentioned in paragraph (2) in connection with the manufacture, distribution or supply of unbranded generic health service medicines and special medicinal products (as applicable to it being a purchaser, seller or both).

(2) The information specified in this paragraph is—

- (a) whether the category of purchaser for each presentation is Category A, B, C or D;
- (b) the quantity of each presentation that is sold or bought;

(a) 2006 c 46.

- (c) the sales income received for each presentation, being the income from the sale of the presentation after deduction of any discounts or rebates or other payments given that can be attributed to the sale of the presentation;
- (d) the amount that is paid for each presentation after deduction of any discounts or rebates or other payments received for the amount paid; and
- (e) the discounts, rebates or other payments given or received for each presentation which cannot be attributed to that presentation.

(3) In the case of unbranded generic health service medicines, the information mentioned in paragraph (1) must be provided to the Secretary of State, in the form that the Secretary of State may specify—

- (a) in respect of the first, second, third and fourth three-month periods of the year beginning on the first day of January, and
- (b) within 28 days of the last day of each three-month period in respect of which the information is provided.

(4) In the case of special medicinal products, the information mentioned in paragraph (1) must be provided to the Secretary of State, in the form that the Secretary of State may specify—

- (a) in respect of the first, second, third and fourth three-month periods of the year, beginning on the first day of February, and
- (b) within 28 days of the last day of each three-month period in respect of which the information is provided.

(5) Paragraph (6) applies here it is not possible to distinguish, in information relating to the purchasing or selling of products, between—

- (a) products that are or were for health service use; and
- (b) products that are or were not for health service use.

(6) Where this paragraph applies, a UK producer may record, keep and provide information on the basis of a best estimate of the sales or purchases that are or were likely to be for health service use, but only if, when it provides the information to the Secretary of State, the producer explains to the satisfaction of the Secretary of State—

- (a) the method of calculating the best estimate; and
- (b) why the information could only be provided on the basis of a best estimate of the sales or purchases that are likely to be for health service use.

(7) In this regulation—

“common name” means the non-proprietary name or if one does not exist the usual common name;

“invented name” is a name which is not the common name and is not liable to be confused with the common name;

“non-proprietary name” means the name which is, or which is a permitted variation of—

- (a) an International Non-Proprietary Name (INN);
- (b) an international Non-proprietary Name Modified (INNМ);
- (c) a British Approved name (BAN);
- (d) an approved name

and for this purpose these names (and their permitted variations) have the same meanings as in the list of names which has been prepared and published under regulation 318 of the 2012 Regulations (list of names) and which is in force;

“special medicinal product” means a medicinal product within the meaning of regulation 167 of the 2012 Regulations, that is used to any extent for the purposes of the health service; and

“unbranded generic health service medicine” means a health service medicine which includes the non-proprietary name of the medicinal product on the labelling of the product but not an invented name.

Provision of information about health service medicines

4.—(1) A relevant UK producer must record and keep the following information in connection with the manufacture, distribution or supply of health service medicines by that producer (as applicable to it being a purchaser, seller or both)—

- (a) the invoices which relate to the sale or purchase of each presentation;
- (b) the name of the purchaser or seller of each presentation;
- (c) the category of purchaser for each presentation (Category A, B, C or D);
- (d) the quantity of each presentation that is sold or bought;
- (e) the sales income received for each presentation, being the income from the sale of the presentation after deduction of any discounts or rebates or other payments given that can be attributed to the sale of the presentation;
- (f) the amount that is paid for each presentation after deduction of any discounts or rebates or other payments received for the amount paid;
- (g) the discounts or rebates or other payments given or received by the producer for each presentation which cannot be attributed to that presentation;
- (h) the terms which apply to any discounts or rebates or other payments mentioned in subparagraphs (e) to (g);
- (i) the name of any person who received the discounts or rebates or other payments mentioned in subparagraphs (e) to (g); and
- (j) whether the presentation is an English health service product, Welsh health service product, Scottish health service product or Northern Ireland health service product.

(2) A relevant UK producer must—

- (a) keep all the information mentioned in paragraph (1) for six years beginning on the date the presentation was sold or purchased on or after the commencement of these Regulations; and
- (b) provide that information to the Secretary of State on written request.

(3) A written request by the Secretary of State—

- (a) may, in particular, specify the period or intervals which the information must relate to, the categories of information to be provided and the form in which the information must be provided and the time period within which the information must be provided to the Secretary of State; and
- (b) must not prevent a small UK producer or primary medical services provider from providing the information in the form of pre-existing documentation, including invoices, where appropriate.

(4) Paragraph (5) applies where it is not possible to distinguish, in information relating to the purchasing or selling of medicines, between—

- (a) medicines that are or were for health service use; and
- (b) medicines that are or were not for health service use.

(5) Where this paragraph applies, a UK producer may record, keep and provide information on the basis of a best estimate of the sales or purchases that are or were likely to be for health service use, but only if, when it provides the information to the Secretary of State, the producer explains to the satisfaction of the Secretary of State—

- (a) the method of calculating the best estimate; and
- (b) why the information could only be provided on the basis of a best estimate of the sales or purchases that are likely to be for health service use.

Provision of information about medical supplies or other related products

5.—(1) A relevant UK producer must record and keep the following information in connection with the manufacture, distribution or supply of any medical supplies or other related products that are UK health service products by that producer (as applicable to it being a purchaser, seller or both)—

- (a) the invoices which relate to the sale or purchase of any products;
- (b) the name of the purchaser or seller of any products;
- (c) the category of purchaser for any products (Category A, B, C or D);
- (d) the quantity of any products that are sold or bought;
- (e) the sales income received for any products, being the income received from the sale of the products after deduction of any discounts or rebates or other payments given that can be attributed to that sale;
- (f) the amount that is paid for any products after deduction of any discounts or rebates or other payments received for the amount paid;
- (g) the discounts, rebates or other payments given or received by the producer which cannot be attributed to a particular product;
- (h) the terms which applied to any discounts or rebates or other payments mentioned in sub-paragraphs (e) to (g);
- (i) the name of any person who received the discounts or rebates or other payments mentioned in sub-paragraphs (e) to (g); and
- (j) whether products are English health service products, Welsh health service products, Scottish health service products or Northern Ireland health service products.

(2) A relevant UK producer must—

- (a) keep all the information mentioned in paragraph (1) for six years beginning on the date of sale or purchase of the medical supplies or other related products on or after the commencement of these Regulations; and
- (b) provide that information to the Secretary of State on written request.

(3) A written request by the Secretary of State—

- (a) may, in particular, specify the period or intervals which the information must relate to, the categories of information to be provided and the form in which the information must be provided and the time period within which the information must be provided to the Secretary of State; and
- (b) must not prevent a small UK producer or primary medical services provider from providing the information in the form of pre-existing documentation, including invoices, where appropriate.

(4) Paragraph (5) applies where it is not possible to distinguish, in information relating to the purchasing or selling of products, between—

- (a) products that are or were for health service use; and
- (b) products that are or were not for health service use.

(5) Where this paragraph applies, a UK producer may record, keep and provide information on the basis of a best estimate of the sales or purchases that are or were likely to be for health service use, but only if, when it provides the information to the Secretary of State, the producer explains to the satisfaction of the Secretary of State—

- (a) the method of calculating the best estimate; and
- (b) why the information could only be provided on the basis of a best estimate of the sales or purchases that are likely to be for health service use.

(6) In this regulation—

“health care professional” has the same meaning as in the 2013 Regulations; and

“medical supplies or other related products” means—

- (a) appliances that are listed in Part IX of the Drug Tariff or in equivalent lists in the Drug Tariffs for Scotland or Northern Ireland;
- (b) foods or dermatological products that—
 - (i) are listed in Part XV of the Drug Tariff or in equivalent lists in the Drug Tariffs for Scotland or Northern Ireland, or
 - (ii) are not so listed but the UK producer in question knows, or it is obvious to a reasonable person in the circumstances, that the foods or dermatological products are being supplied on NHS prescription to patients for the prevention, diagnosis, treatment or management of clinical conditions;
- (c) appliances, foods or dermatological products that the UK producer in question knows, or it is obvious to a reasonable person in the circumstances, are being supplied to patients of hospitals (which may not be UK health service hospitals), in pursuance of prescriptions or directions from health care professionals, for the prevention, diagnosis, treatment or management of clinical conditions; and
- (d) appliances, foods and dermatological products that are available for purchase under an NHS framework agreement and are for supply to patients, in pursuance of prescriptions or directions from health care professionals, for the prevention, diagnosis, treatment or management of clinical conditions.

Information notices and written requests about manufacturing costs etc.

6.—(1) Where the Secretary of State, in pursuance of the statutory purpose, requires information from a relevant UK Producer that manufactures or distributes UK health service products in respect of the costs incurred by the producer in connection with the manufacturing, distribution or supply of a particular UK health service product (other than costs which relate to any transaction between the producer and another UK producer for that product)—

- (a) the Secretary of State must give a UK producer an information notice (the terms of which are provided for in section 264A(6) of the 2006 Act); and
- (b) the producer must comply with that notice.

(2) If a relevant UK Producer that manufactures or distributes UK health service products receives a written request by the Secretary of State, in pursuance of the statutory purpose, for information about costs as mentioned in paragraph (6)(b) that—

- (a) relates to a transaction between the producer and another UK producer (other than information that could be required by an information notice under paragraph (1)); or
- (b) is aggregated company data, not relating particular UK health service products but which it is obvious to a reasonable person in the circumstances could contribute (directly or indirectly) towards achievement of the statutory purpose.

(3) That request may, in particular, specify—

- (a) the period or intervals which the information must relate to;
- (b) the categories of information to be provided;
- (c) the form in which the information must be provided; and
- (d) the time period within which the information must be provided to the Secretary of State.

(4) Paragraph (5) applies where, for the purposes of complying with an information notice under paragraph (1) or a request under paragraph (2)(a), it is not possible to distinguish, in information relating to costs, between costs that are attributable to—

- (a) products that are or were for health service use and those that are or were not for health service use; or
- (b) particular presentations or descriptions of products and other presentations or descriptions of those products.

(5) Where this paragraph applies, a UK producer may provide information on the basis of a best estimate, but only if, when it provides the information to the Secretary of State, the producer explains to the satisfaction of the Secretary of State—

- (a) the method of calculating the best estimate; and
- (b) why the information could only be provided on the basis of a best estimate.

(6) A relevant UK Producer that manufactures or distributes UK health service products must record and keep information that it is likely to need if it is to comply with a information notice under paragraph (1) or a reasonable request under paragraph (2)(a), such information being information—

- (a) that it is obvious to a reasonable person in the circumstances that a UK producer could reasonably be expected to record and keep for the ordinary and proper conduct of its business, having regard to the desirability for any business of understanding its own costs; and
- (b) relating to (if these are costs to the UK producer)—
 - (i) manufacturing costs,
 - (ii) supply costs,
 - (iii) distribution costs,
 - (iv) research and development costs,
 - (v) capital costs,
 - (vi) the business costs; and
 - (vii) any other costs related to the manufacture, distribution or supply of that product that may be relevant to the statutory purpose.

(7) The information mentioned in paragraph (6) must be kept by the producer for a period of six years beginning on the date on which it is or was first recorded, but this requirement does not apply to any information that the producer has ceased to keep before the coming into force of these Regulations.

(8) In this regulation, “the statutory purpose” means the purpose in section 264A(3) of the 2006 Act.

Urgent provision of information about a specified English health service medicine with a price listed in Part VIII of the Drug Tariff

7.—(1) A UK producer that—

- (a) manufactures or distributes health service medicines; or
- (b) not being the manufacturer or distributor of health service medicines, is an importer of health service medicines who supplies those medicines,

must provide the information mentioned in paragraph (2) to the Secretary of State within 24 hours of receipt of a request specifying the presentation of an English health service medicine which the Secretary of State seeks information about.

(2) The information to be provided by a UK producer under paragraph (1) is—

- (a) the quantity of the specified presentation available for distribution or supply to NHS chemists in England by that producer; and
- (b) the prices to be charged for the specified presentation by that producer.

(3) The Secretary of State may make a request to a UK producer for that information only if the Secretary of State considers that the specified presentation of English health service medicine is not available for distribution or supply by that producer to a NHS chemist or primary medical services provider at the price listed for that medicine in Part VIII of the Drug Tariff.

Provision of information about discontinuation or supply shortage of health service medicines

8.—(1) For the purposes of this regulation, the designated UK producer, in relation to a presentation of a health service medicine, is—

- (a) in the case of an authorised health service medicine, the holder of the authorisation for that presentation if that person also manufactures, distributes or supplies that medicine; or
- (b) in any other case, the person in the United Kingdom who is the manufacturer of that presentation or the person who imports that presentation into the United Kingdom.

(2) A designated UK producer must provide the information mentioned in paragraph (3) to the Secretary of State if that producer—

- (a) is to discontinue the manufacture or supply of any presentation of health service medicine; or
- (b) considers there will be a supply shortage of any presentation of health service medicine, which would result in 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.

(3) The information to be provided to the Secretary of State in the circumstances mentioned in paragraph (2) is as follows—

- (a) the name of the presentation;
- (b) the licensed uses of the presentation and the unlicensed uses of the presentation that are known to the designated UK producer;
- (c) the reasons for the discontinuation or supply shortage;
- (d) the anticipated duration of the supply shortage;
- (e) the amount of stock held by the producer for that presentation;
- (f) the anticipated date, if any, of the next delivery of the presentation;
- (g) the designated UK producer's market share for the presentation;
- (h) the steps taken, if any, to address any anticipated supply shortage;
- (i) the name and contact details of a representative for the UK producer who can provide updated information to the Secretary of State and answer any queries he may have about the supply shortage or discontinuation.

(4) The designated UK producer must provide the information mentioned in paragraph (3) to the Secretary of State at least 6 months prior to any anticipated impact on patients resulting from the discontinuation or supply shortage, or if that is not possible, as soon as the producer is aware of any supply shortage or discontinuation.

Urgent provision of information about the availability of health service medicines

9.—(1) A UK producer that—

- (a) manufactures or distributes health service medicines; or
- (b) not being the manufacturer or distributor of health service medicines, is an importer of health service medicines who supplies those medicines,

must provide the information mentioned in paragraph (2) to the Secretary of State within 24 hours of receipt of a request specifying the presentation of a health service medicine which the Secretary of State seeks information about.

(2) The information to be provided by a UK producer under paragraph (1) is—

- (a) the quantity of the specified presentation of health service medicine that is available for distribution or supply by that producer; and
- (b) the availability, if any, of other health service medicines which may be used as therapeutic alternatives to the specified presentation.

(3) The Secretary of State may make a request to a UK producer for that information only if the Secretary of State considers that there is a supply shortage of the specified presentation of health service medicine.

Disclosure of Information to Bodies representing UK Producers

10.—(1) The following bodies are prescribed under section 264B(1)(k) of the 2006 Act as bodies appearing to the Secretary of State to represent UK producers—

- (a) the Association of British Healthcare Industries;
- (b) the Association of the British Pharmaceutical Industry;
- (c) the Association of Pharmaceutical Specials Manufacturers;
- (d) the British Generic Manufacturers Association;
- (e) the British Medical Association;
- (f) the Healthcare Distribution Association;
- (g) the Pharmaceutical Services Negotiating Committee;
- (h) the Dispensing Doctor's Association;
- (i) the British Healthcare Trades Association;
- (j) the British In Vitro Diagnostics Association;
- (k) the Proprietary Association of Great Britain;
- (l) the British Association of European Pharmaceutical Distributors;
- (m) the BioIndustry Association; and
- (n) the Ethical Medicines Industry Group.

(2) The following purposes are prescribed under section 264B((3)(g) of the 2006 Act—

- (a) in relation to the bodies mentioned in paragraphs (1)(a), (i), (j) or (k), the purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(l);
- (b) in relation to the bodies mentioned in paragraphs (1)(b), (m) or (n), the purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(l) or (m);
- (c) in relation to the bodies mentioned in paragraphs (1)(c), (d), (f), or (l) the purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(a), (b) or (l);
- (d) in relation to the bodies mentioned in paragraphs (1)(e) or (h), the purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(a); and
- (e) in relation to the body mentioned in paragraph (1)(g), the purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(b).

Enforcement

11.—(1) If the Secretary of State considers that the information required to be provided by regulations 3(3) and (4), 4(2)(b), 5(2)(b), 6(1) and (2), 7(1), 8(2) and 9(1) is incomplete or inaccurate, or not in the form that the Secretary of State may specify, the Secretary of State may request that further information is provided by the UK producer within a month of receipt of such a written request.

(2) A UK producer who fails to provide information to the Secretary of State as required by regulations 3(3) and (4), 4(2)(b), 5(2)(b), 6(1) and (2), 7(1), 8(2) and 9(1), or who fails to provide further information as required by paragraph (1), must, on demand of the Secretary of State, pay a daily penalty for that contravention in accordance with the amount specified in the Schedule.

(3) A demand made by the Secretary of State under paragraph (2) must be made by notice in writing addressed to the UK producer in question and it must state—

- (a) the amount of the penalty calculated up to the date of the demand;
- (b) the period within which the penalty must be paid; and
- (c) the UK producer's appeal rights.

Appeals

12.—(1) Any UK producer, in respect of whom the Secretary of State has made an enforcement decision under these Regulations, has a right of appeal against that decision in accordance with the Health Service Medicines (Price Control Appeal) Regulations 2000(a).

(2) In this regulation an enforcement decision includes any decision relating to information that is required by virtue of an information notice under section 264A(5) of the 2006 Act.

Review

13.—(1) The Secretary of State must—

- (a) carry out a review of the regulatory provision contained in these Regulations; and
- (b) publish a report setting out the conclusions of that review.

(2) The first report must be published on or before 1st January 2019 and subsequent reports must be published at annual intervals.

(3) Section 30(4) of Small Business, Enterprise and Employment Act 2015(b) requires that the reports published under this regulation must, in particular –

- (a) set out the objectives intended to be achieved by the regulatory provision referred to in paragraph (1)(a),
- (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 provision.

(4) In this regulation, “regulatory provision” has the same meaning as in sections 28 to 32 of the 2015 Act (see section 32 of that Act).

Signed by authority of the Secretary of State for Health

Date

Name
Title
Department of Health

SCHEDULE

Regulation 11(2)

1. The daily penalty payable by a UK producer for failing to provide information to the Secretary of State as required by regulations 3(2) and (3), 4(2)(b), 5(2)(b), 6(1) and (2), 7(1), 8(1), 9(1), or 11(1) must be calculated by reference to the entries in Columns (1), (2) and (3) of Table 1, as follows—

- (a) Column (1), specifies the UK producer's total annual turnover in the United Kingdom, which is as stated in the producer's most recent submitted accounts;
- (b) Column (2) specifies the daily penalty which accrues for the first 14 days of contravention by reference to the producer's total annual turnover in the United Kingdom;

(a) S.I. 2000/124; the relevant amending instrument is S.I. 2000/870.
(b) 2015 c.26.

- (c) Column (3) specifies, the daily penalty which accrues on the 15th day, and each subsequent day, of contravention by reference to the producer's total annual turnover in the United Kingdom.

Table 1

Daily penalty payable by reference to the annual total turnover in the United Kingdom

<i>Column (1)</i>	<i>Column (2)</i>	<i>Column (3)</i>
<i>Total annual turnover in the United Kingdom</i>	<i>Daily penalty for first 14 days</i>	<i>Daily penalty for subsequent days</i>
Less than £100 million	£2,500	£5,000
£100 million or more	£5,000	£10,000

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations provide for UK producers to record and keep certain information which the Secretary of State may require to enable or facilitate any of the specified purposes in section 264A(3) of the National Health Service Act 2006.

These Regulations also require UK producers, or categories of them, to provide specified information to the Secretary of State in relation to prescribed periods, at prescribed intervals (including on written request or pursuant to an information notice), in a prescribed form and manner, at a prescribed time or within a prescribed period.

Information provided to the Secretary of State under these Regulations may be disclosed to the bodies listed in regulation 10(1), as bodies appearing to the Secretary of State to represent UK producers. Those bodies may not use any confidential or commercially sensitive information disclosed to them by the Secretary of State for any purpose other than the purposes prescribed in regulation 10(2), in relation to that body.

If the Secretary of State considers that a UK producer has provided incomplete or inaccurate information, or it is not in the specified form, he may write to the producer requesting that further information be provided within a month of such a request (see regulation 11(1)).

Any producer who fails to provide information to the Secretary of State as required by these regulations is liable to pay, on demand, a daily penalty for that contravention in accordance with the amount specified in the Schedule to these Regulations.

A UK producer, in respect of whom an enforcement decision is made under these Regulations has a right of appeal in accordance with the Health Service Medicines (Price Control Appeals) Regulations 2000 (S.I. 2000/124).

Regulation 13 requires the Secretary of State to review the operation and effect of these Regulations and publish a report setting out the conclusions of that review a year after the commencement of these provisions and annually after that.

An impact assessment relating to this instrument has been prepared and copies can be obtained from the Department of Health, Wellington House, 133-155 Waterloo Road, London SE1 8UG.