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STATUTORY INSTRUMENTS

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**2018 No. 677**

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

**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 NHS Digital 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.

**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.