

---

STATUTORY INSTRUMENTS

---

**2018 No. 677**

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

**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(1) 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.

**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 NHS Digital 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.

---

**Status:** *This is the original version (as it was originally made).*

---