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.

(**1**) Regulation 167 of the 2012 Regulations was amended by S.I. 2017/715.

(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.