
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

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.

Changes to legislation:

There are currently no known outstanding effects for the The Health Service Products (Provision and Disclosure of Information) Regulations 2018, Section 11.