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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 5**

Information about costs incurred in connection with the manufacturing, distribution or supply of UK health service products

**Provision of general information about costs incurred in connection with the manufacture or distribution of health service medicines and appliances**

**26.**—(1) If the Secretary of State requires the information for the statutory purpose, the Secretary of State may by request, in writing, require a UK producer—

- (a) to provide information about any costs incurred by the producer—
  - (i) in connection with the manufacturing or distribution of a particular presentation of health service medicine, and
  - (ii) which relate to any transaction between the producer and a UK producer for that presentation;
- (b) to provide information about any costs incurred by the producer—
  - (i) in connection with the manufacturing or distribution of a particular appliance which—
    - (aa) is a UK health service product, and
    - (bb) is, in the month in which the request is made, listed in a Drug Tariff, and
  - (ii) which relate to any transaction between the producer and a UK producer for that appliance;
- (c) to provide information about any costs (other than supply costs) incurred by the producer in connection with the manufacturing, or distribution of—
  - (i) any health service medicine, or
  - (ii) any appliance which is—
    - (aa) a UK health service product, and
    - (bb) in the month in which the request is made, listed in a Drug Tariff.

(2) But a request under paragraph (1)(a), (b) or (c) may not require a UK producer to provide any information which the producer could not reasonably be expected to record and keep for the purpose of understanding the producer's relevant costs.

(3) In addition, a request under paragraph (1)(c) may not require a UK producer to provide any information to which regulation 25 applies.

(4) A UK producer who is given a written request under paragraph (1)(a), (b) or (c) must comply with the request.

- (5) The 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.
- (6) The producer must provide the requested information within the period of 28 days beginning with the day on which the producer is given the request.