#### STATUTORY INSTRUMENTS

### 2018 No. 677

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

## PART 5 U.K.

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 U.K.

- **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 [FINHS England] 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.

#### **Textual Amendments**

Words in reg. 26(5)(b) substituted (1.2.2023) by The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98), reg. 1(2), Sch. para. 58(6) (with reg. 3)

## **Changes to legislation:**

There are currently no known outstanding effects for the The Health Service Products (Provision and Disclosure of Information) Regulations 2018, Section 26.