
STATUTORY INSTRUMENTS

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 information about costs incurred in connection with the manufacture or distribution of a particular health service medicine or appliance

25.—(1) If the Secretary of State requires the information for the statutory purpose, the Secretary of State may by information notice⁽¹⁾ require a UK producer to provide specified information in respect of any relevant costs incurred by the producer—

- (a) in connection with the manufacturing of a particular presentation of unbranded generic health service medicine or special health service medicine;
- (b) in connection with the distribution or supply of a particular presentation of health service medicine;
- (c) in connection with the manufacturing, supply or distribution of a particular appliance which—
 - (i) is a UK health service product, and
 - (ii) is, in the month in which the request is made, listed in a Drug Tariff.

(2) But the Secretary of State 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) An information notice must specify the statutory purpose for which the specified information is required.

(4) A UK producer must comply with any information notice given to the producer.

(5) In this regulation—

“relevant costs”, in relation to a producer, means any costs (including, for example, manufacturing costs, supply costs, distribution costs, research and development cost, capital costs and business costs) other than costs which relate to any transaction between the producer and a UK producer for the relevant health service product;

“specified” means specified in an information notice.

(1) See the definition of “information notice” in section 264A(6) of the National Health Service Act 2006.

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.