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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 4**

General information about supply of UK health service products

**Information to be recorded and kept about supply of health service medicines other than imported special health service medicines: other UK producers**

**18.**—(1) A UK producer must—

- (a) record the information mentioned in paragraph (2) for—
  - (i) each supply by the producer of a presentation of relevant health service medicine which the producer has manufactured, and
  - (ii) each supply by the producer (otherwise than as a medicines wholesaler) of any presentation of relevant health service medicine, and
- (b) keep that information for a period of four years beginning with the day on which it is recorded.

(2) The information is—

- (a) the name of the person to whom the presentation is supplied (“the purchaser”),
- (b) if known to the producer, whether the purchaser is in Category A, B, C or D,
- (c) the quantity, by pack size, supplied to the purchaser,
- (d) the net sales income, or a reasonable estimate of the net sales income, for the supply of the presentation to the purchaser,
- (e) the terms on which any discounts, payments, or payments or benefits in kind taken into account when calculating the net sales income were given by the producer,
- (f) the name of the person to whom those discounts were given, if that person is not the purchaser,
- (g) if known to the producer, whether the presentation is an English health service product, a Welsh health service product, a Scottish health service product or a Northern Ireland health service product, and
- (h) if it is a presentation of made special health service medicine, the excipient formulations supplied (if any).

(3) In this regulation, “relevant health service medicine” means a health service medicine other than an imported special health service medicine.