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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 imported special health service medicines: medicines wholesalers and importers**

- 16.**—(1) A UK producer who is a medicines wholesaler or an importer must—
- (a) record the information mentioned in paragraph (2) for each purchase by the producer of a presentation of imported special health service medicine for supply, 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 from whom the presentation is purchased,
  - (b) the quantity of packs purchased,
  - (c) the net purchase amount, or a reasonable estimate of the net purchase amount, for the purchase,
  - (d) the terms on which any discounts, payments, or payments or benefits in kind taken into account when calculating that amount were received, and
  - (e) the name of the person to whom the discounts, payments, or payments or benefits in kind were given, if that person is not the producer.
- (3) A UK producer who is a medicines wholesaler or an importer must also—
- (a) record the information mentioned in paragraph (4) for each supply of a presentation of imported special health service medicine by the producer, and
  - (b) keep that information for a period of four years beginning with the day on which it is recorded.
- (4) 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 of packs supplied,
  - (d) the net sales income, or a reasonable estimate of the net sales income, for the supply,
  - (e) the terms on which the discounts, payments, or payments or benefits in kind taken into account when calculating that income were given by the producer,
  - (f) the name of the person to whom any of those discounts, payments, or payments or benefits in kind were given, if that person is not the purchaser, and

- (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.