
STATUTORY INSTRUMENTS

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: medicines wholesalers

- 17.—(1) A UK producer who is a medicines wholesaler must—
- (a) record the information mentioned in paragraph (3) for each purchase by the producer of a relevant presentation of health service medicines for supply (including any purchase which requires the presentation to be imported into the United Kingdom), 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, by pack size, purchased,
 - (c) the net purchase amount, or a reasonable estimate of the net purchase amount, for the purchase,
 - (d) the terms on which the discounts, payments, or payments or benefits in kind taken into account when calculating that amount were given,
 - (e) the name of the person to whom the discounts, payments, payments or benefits in kind were given, if that person is not the wholesaler, and
 - (f) if it is a presentation of made special health service medicine, the excipient formulations purchased (if any).
- (3) A UK producer who is a medicines wholesaler must also—
- (a) record the information mentioned in paragraph (4) for each supply by the wholesaler of a relevant presentation of health service medicine, 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, by pack size, supplied,
 - (d) the net sales income, or a reasonable estimate of the net sales income, for the supply to the purchaser,

- (e) the terms on which any 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 any discounts, payments, or payments or benefits in kind were given, if that person is not the purchaser,
 - (g) if it is a presentation of made special health service medicine, the excipient formulations supplied (if any), and
 - (h) 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.
- (5) In this regulation, “relevant presentation of health service medicine”, in relation to a producer, means a presentation of health service medicine other than—
- (a) a presentation which the producer has manufactured, or
 - (b) a presentation of imported special health service medicine.

Changes to legislation:

There are currently no known outstanding effects for the The Health Service Products (Provision and Disclosure of Information) Regulations 2018, Section 17.