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.