STATUTORY INSTRUMENTS

2018 No. 677

The Health Service Products (Provision and Disclosure of Information) Regulations 2018

PART 2

Quarterly information about unbranded generic health service medicines

Information to be recorded and kept about supply of unbranded generic health service medicines: manufacturers and importers

7.—(1) A relevant producer must record the information mentioned in paragraph (3) for each presentation of unbranded generic health service medicine which—

(a) the producer manufactures, or imports, and supplies to any of the following—

(i) a UK primary medical services provider,

(ii) a Health Service chemist, or

(iii) a medicines wholesaler,

(b) is, in the month in which the producer supplies it, listed in a Drug Tariff, and

(c) if it is a liquid or a topical preparation**,** or is in tablet or capsule form, is in a pack not exceeding the maximum pack size.

(2) The relevant producer must keep the information recorded under paragraph (1) until it is provided to the Secretary of State in accordance with regulation 9.

(3) The information is—

(a) the number of packs supplied to persons mentioned in paragraph (1)(a)(i) to (iii), and

(b) the net sales income, or a reasonable estimate of the net sales income, from that supply.

(4) In this regulation, "relevant producer" means—

(a) a manufacturer(**1**), or

(b) a UK producer who is an importer.

(**1**) See section 266(6) of the National Health Service Act 2006 (c. 41) for the definition of "manufacturer".