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

Meaning of "unbranded generic health service medicine" and listing of a presentation of unbranded generic health service medicine

6.—(1) In these Regulations, "unbranded generic health service medicine" means a health service medicine(**1**) the labelling of which includes the common name of the product, but does not include an invented name.

(2) For the purposes of paragraph (1)—

"invented name" means a name which—

(a) is not the common name of the medicinal product, and

(b) is not liable to be confused with that name;

"non-proprietary name" means a name which is, or is a permitted variation of—

(a) an International Non-proprietary Name (INN),

(b) an International Non-proprietary Name Modified (INNM),

(c) a British Approved Name (BAN),

(d) a British Approved Name Modified (BANM), or

(e) an approved name.

(3) The names mentioned in paragraphs (a) to (e) of the definition of "non-proprietary name" (and their permitted variations) have the same meanings as in a list of names which has been prepared and published under regulation 318 of the 2012 Regulations and which is in force(**2**).

(4) For the purposes of this Part, a presentation of unbranded generic health service medicine is listed in a Drug Tariff if a price for that presentation is listed—

(a) in the Drug Tariff (England)(**3**) for the given month,

(b) in the Drug Tariff (Wales)(**4**) for the given month,

(**1**) See section 266(6) of the National Health Service Act 2006 for the definition of "health service medicine".

(**2**) Copies of the list can be obtained from: https://www.pharmacopoeia.com/what-is-the-ban-book or The Stationery Office, PO Box 29, Norwich, NR3 1GN.

(**3**) The Drug Tariff (England) is available at https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff or from NHS Business Services Authority, Stella House, Goldcrest Way, Newburn Riverside, Newcastle upon Tyne, NEI5 8NY.

(**4**) The Drug Tariff (Wales) is available at https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff or from NHS Business Services Authority, Stella House, Goldcrest Way, Newburn Riverside, Newcastle upon Tyne, NEI5 8NY.

(c) in the Drug Tariff (Scotland)(**5**) for the given month, or

(d) in the Drug Tariff (Northern Ireland)(**6**) for the given month.

(5) For the purposes of determining whether a reimbursement price is listed for a presentation, any pack size specified in the relevant Drug Tariff is to be disregarded.

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(**7**), or

(b) a UK producer who is an importer.

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

8.—(1) A UK producer who is a medicines wholesaler must—

(a) record the information mentioned in paragraph (2) for each presentation of unbranded generic health service medicine which the producer purchases for supply (including any purchase which requires the presentation to be imported into the United Kingdom) and—

(i) which is, in the month in which producer purchases it, listed in a Drug Tariff, and

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

(b) keep that information until it is provided to the Secretary of State in accordance with regulation 9.

(2) The information is—

(a) the number of packs purchased, and

(**5**) The Drug Tariff (Scotland) is available at http://www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/Scottish-Drug-Tariff/ or from Information Services Division, NHS National Services Scotland, Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB.

(**6**) The Drug Tariff (Northern Ireland) is available at http://www.hscbusiness.hscni.net/services/2034.htm or from Business Services Organisation Headquarters, 2 Franklin Street Belfast, BT2 8DQ.

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

(b) the net purchase amount, or a reasonable estimate of the net purchase amount, for that purchase.

(3) A UK producer who is a medicines wholesaler must also—

(a) record the information mentioned in paragraph (4) for each presentation of unbranded generic health service medicine (other than a presentation which the wholesaler has manufactured) which—

(i) the producer supplies to any UK primary medical services provider or Health Service chemist,

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

(iii) if it is a liquid or a topical preparation**,** or is in tablet or capsule form, is in a pack which does not exceed the maximum pack size, and

(b) keep that information until it is provided to the Secretary of State in accordance with regulation 9.

(4) The information is—

(a) the number of packs supplied to persons mentioned in paragraph (3)(a)(i), and

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

Requirement to provide information about supply of unbranded generic health service medicines

9.—(1) A UK producer must provide the information which the producer is required to record and keep under regulation 7 or 8 to the Secretary of State in accordance with this regulation.

(2) The information must be provided, in each year, for the following quarterly periods—

(a) 1st July to 30th September;

(b) 1st October to 31st December;

(c) 1st January to 31st March;

(d) 1st April to 30th June.

(3) The information for a quarterly period must be provided—

(a) in an electronic spreadsheet provided for that purpose by the Secretary of State, or

(b) if the Secretary of State does not provide such a spreadsheet, via the NHS Digital online gateway.

(4) The information for a quarterly period must be provided within the period of 28 days beginning with the first day of the month which begins immediately after the end of that quarterly period.