
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 (INN^M),
- (c) a British Approved Name (BAN),
- (d) a British Approved Name Modified (BAN^M), 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, NE15 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, NE15 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.

(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.