STATUTORY INSTRUMENTS

2018 No. 677

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

PART 6

Information about price and availability of health service medicines

Provision of information about English health service medicines which are not available at the reimbursement price

27.—(1) This regulation applies where the Secretary of State has reasonable grounds to suspect that a presentation of English health service medicine is, in a particular month, available for distribution or supply to English NHS chemists at a price which exceeds the listed price.

(2) Where this regulation applies, the Secretary of State may, by request in writing, require any of the following UK producers to provide the information mentioned in paragraph (3) for the relevant presentation—

(a) a manufacturer of the presentation,

(b) a person who distributes the presentation (whether by wholesale dealing or otherwise), or

(c) an importer of the presentation.

(3) The information is—

(a) the quantity, by relevant pack size, of the presentation which is available for distribution or supply by the producer in England,

(b) the net price or net prices, or a reasonable estimate of the net price or net prices, at which the producer would offer to distribute or supply those pack sizes in England,

(c) the quantity, by relevant pack size, of any branded equivalent which is available for distribution or supply by the producer in England, and

(d) the net price or net prices, or a reasonable estimate of the net price or net prices, at which the producer would offer to distribute or supply those pack sizes in England.

(4) A producer who is given a written request under paragraph (2), must comply with the request within the period of two working days beginning—

(a) with the day on which producer is given the request, if that day is a working day;

(b) otherwise, with the first working day after the day on which the notice is given to the producer.

(5) In this regulation—

"branded equivalent", in relation to a presentation of English health service medicine, means a particular form of medicinal product—

(a) to which a brand name has been applied that enables the medicine to be identified without reference to the common name, but

(b) which has the same—

(i) active ingredient or ingredients,

(ii) strength,

(iii) physical form,

(iv) unit dose (if applicable),

(v) method of administration (if applicable),

(vi) freeness (if applicable), and

(vii) type of packaging,

as the presentation;

"English health service medicine" means a medicinal product used to any extent for the purposes of the health service continued under section 1(1) of the 2006 Act;

"listed price", in relation to a presentation of English health service medicine, means the price listed for that medicine in Part VIII of the Drug Tariff (England);

"net price", in relation to a presentation, means the price after the deduction of—

(a) all discounts and payments, and

(b) the value of all payments or benefits in kind;

"relevant pack size"—

(a) in relation to a presentation of English health service medicine which—

(i) is a presentation of unbranded generic health service medicine, and

(ii) is a liquid or a topical preparation or is in tablet or capsule form,

means any pack size which does not exceed the maximum pack size;

(b) in relation to any other presentation of English health service medicine or a branded equivalent, means any pack size.

(6) For the purposes of this regulation—

(a) the definition of "presentation" in paragraph 2 of Schedule 1 applies as if any reference to pack size were omitted, and

(b) for the purpose of determining whether there is price listed in Part VIII of the Drug Tariff (England), any pack size specified in that Part is to be disregarded.

Provision of information about availability of health service medicines

28.—(1) This regulation applies where the Secretary of State considers that there is a supply shortage of a presentation of health service medicine (the "relevant presentation").

(2) Where this regulation applies, the Secretary of State may by notice in writing require any of the following to provide the information mentioned in paragraph (3) about the relevant presentation—

(a) a manufacturer of the presentation,

(b) a person who distributes the presentation (whether by wholesale dealing or otherwise), or

(c) an importer of the presentation.

(3) The information is—

(a) the quantity (if any) of packs of the relevant presentation that is available for supply by the producer, and

(b) the quantity (if any) of any alternative presentation specified in the request that is available for supply by the producer.

(4) A producer who is given a notice under paragraph (2) must comply with the request within the period of two working days beginning—

(a) with the day on which producer is given the request, if that day is a working day;

(b) otherwise, with the first working day after the day on which the notice is given to the producer.

(5) In this regulation, "alternative presentation", in relation to a relevant presentation, means a presentation of health service medicine which is used as a therapeutic alternative to the relevant presentation.

Requirement to provide information about discontinuation or anticipated supply shortage of certain health service medicines

29.—(1) This regulation applies where a designated producer of a notifiable presentation—

(a) intends to discontinue the manufacturing or supply of the presentation and considers that this is likely to have a direct impact on any patient who takes, or may need to take, the presentation for the prevention or treatment of a physical or mental illness, or

(b) considers there is likely to be a supply shortage of the presentation which will have a direct impact on any patient who takes, or may need to take, the presentation for the prevention or treatment of a physical or mental illness.

(2) Where this regulation applies, the designated producer must provide the following information to the Secretary of State—

(a) the name of the presentation,

(b) the licensed uses of the presentation which the producer is aware of,

(c) the unlicensed uses of the presentation which the producer is aware of,

(d) the reasons for which the manufacturing or supply is to be discontinued or, as the case may be, the producer considers there is likely to be a supply shortage,

(e) the quantity of the presentation which the producer has available for supply,

(f) where the producer considers there is likely to be a supply shortage—

(i) the anticipated duration of the shortage;

(ii) any steps taken by the producer to address it,

(g) the producer's estimated share of the market,

(h) whether the presentation is made available under an NHS framework contract, and

(i) the name and contact details of a representative of the producer.

(3) The information must be provided—

(a) where the producer intends to discontinue the manufacturing or supply of the relevant presentation—

(i) at least six months before the day on which the manufacturing or supply will cease, or

(ii) where the decision to discontinue the manufacturing or supply is made less than six months before the day on which manufacturing or supply will cease, as soon as reasonably practicable after the producer makes the decision;

(b) where the producer considers there may be a supply shortage of the relevant presentation—

(i) at least six months before any anticipated impact on any patient who takes the presentation is realised, or

(ii) where the producer becomes aware of the likely supply shortage less than six months before the producer considers any anticipated impact will be realised, as soon as

reasonably practicable after the producer becomes aware that there may be a supply shortage.

(4) In this regulation—

"notifiable presentation" means a presentation of health service medicine in respect of which a marketing authorisation has been granted other than a presentation of such medicine in respect of which a parallel distribution notice(**1**) with the United Kingdom as the Member State of destination has been given;

"designated producer", in relation to a notifiable presentation, means—

(a) the UK producer who holds the marketing authorisation for the presentation, if that producer manufactures the presentation;

(b) otherwise, a UK producer who manufactures the presentation or imports the presentation and supplies it by way of sale;

"marketing authorisation" has the meaning given in regulation 8(1) of the 2012 Regulations.

(**1**) See Article 57(1)(o) of Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ NO L 136, 30.04.2004, p1), as last amended by Regulation 1072/2012 of the European Parliament and of the Council of 25 October 2012 (OJ No L 316, 14.11.2012, p38).