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

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 **[**F1UK**]** marketing authorisation has been granted F2...

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

(a) the UK producer who holds the **[**F3UK**]** 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;

"**[**F4UK**]** marketing authorisation" has the meaning given in regulation 8(1) of the 2012 Regulations.

Textual Amendments

F1 Word in reg. 29(4) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 8 para. 15(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Words in reg. 29(4) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 8 para. 15(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F3 Word in reg. 29(4) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 8 para. 15(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F4 Word in reg. 29(4) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 8 para. 15(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation:
There are currently no known outstanding effects for the The Health Service Products (Provision and Disclosure of Information) Regulations 2018, Section 29.