
STATUTORY INSTRUMENTS

2018 No. 677

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

PART 8

Enforcement and appeals

Compliance procedure

31.—(1) If the Secretary of State considers that a UK producer—

- (a) has not complied with regulation 9, 14 or 29,
- (b) has provided information under regulation 9, 14 or 29 which is incorrect or incomplete,
- (c) has not complied with a written request given to the producer under regulation 23, 24, 26, 27, 28 or 30 (“the original request”), or
- (d) has provided information in response to an original request which is incorrect or incomplete,

the Secretary of State may by notice in writing require the producer to provide any of the relevant information or to provide relevant information which is accurate.

Such a notice is referred to in these Regulations as a “compliance notice”.

(2) A compliance notice must—

- (a) specify the provision of these Regulations or the original request to which the notice relates,
- (b) specify the relevant information to be provided to the Secretary of State,
- (c) state the additional compliance period within which that information is to be provided,
- (d) state that the Secretary of State may demand a penalty from the producer if the information is not provided within that period, and
- (e) state that there is a right of appeal against the compliance notice in accordance with the 2000 Regulations.

(3) For the purposes of paragraph (2), “additional compliance period”—

- (a) in relation to a compliance notice which relates to regulation 9, 14 or 29, means the period of seven working days beginning—
 - (i) with the day on which the compliance notice is given to the producer, if that day is a working day;
 - (ii) otherwise, with the first working day after the day on which the compliance notice is given to the producer;
- (b) in relation to a compliance notice which relates to an original request made under regulation 27 or 28, means the period of one working day beginning—

- (i) with the day on which the compliance notice is given to producer, if that day is a working day;
 - (ii) otherwise, with the first working day after the day on which it is given to the producer;
 - (c) in any other case, means the period of 30 working days beginning—
 - (i) with the day on which it is given to the producer, if that day is a working day;
 - (ii) otherwise, with the first working day after the day on which it is given to the producer.
- (4) But where the original request was made under regulation 23, the Secretary of State may, instead of the period mentioned in paragraph (3)(c), specify an additional compliance period of seven working days beginning—
- (a) with the day on which it is given to the producer, if that day is a working day, or
 - (b) otherwise, with the first working day after the day on which it is given to the producer.
- (5) A UK producer who is given a compliance notice must comply with that notice.
- (6) If a UK producer—
- (a) is given a compliance notice in relation to an original request, and
 - (b) the producer is a small producer in connection with that request,
- the producer may provide any or all of the required information specified in the notice in the form of an invoice or other existing document.
- (7) For the purposes of paragraph (6), whether a UK producer is a small producer is to be determined in accordance with Schedule 2.
- (8) In this regulation, “relevant information”, in relation to a producer, means any of the information—
- (a) the producer is required to provide to the Secretary of State under regulation 9, 14 or 29, or
 - (b) specified in the original request.

Penalties

- 32.**—(1) This regulation applies where a UK producer contravenes regulation 25(4) or 31(5).
- (2) Where this regulation applies—
- (a) the producer is liable to pay a penalty to the Secretary of State, and
 - (b) the amount of the penalty is to be determined in accordance with paragraphs (3) and (4).
- (3) If the producer contravenes regulation 31(5) by failing to comply with a compliance notice relating to regulation 27 or 28, the amount of the penalty is a single penalty of £1,000.
- (4) If the producer contravenes regulation 25(4), or contravenes regulation 31(5) by failing to comply with any other compliance notice, the amount of the penalty is a daily penalty and is to be calculated—
- (a) if the producer is a small producer, in accordance with paragraph 2 of Schedule 3;
 - (b) in the case of any other producer, in accordance with paragraph 3 of Schedule 3.
- But this paragraph is subject to paragraphs (9) and (10).
- (5) Whether a UK producer is a small producer is to be determined in accordance with Schedule 2.
- (6) Where a producer is liable to pay a penalty under this regulation, the Secretary of State may by demand in writing require the producer to pay that penalty to the Secretary of State.
- (7) A written demand under paragraph (6) must—

- (a) specify—
 - (i) if the penalty payable by the producer is a single penalty, that the amount of the penalty is £1,000;
 - (ii) if the penalty payable by the producer is a daily penalty, the information mentioned in paragraph (8);
 - (b) give the Secretary of State’s reasons for imposing the penalty;
 - (c) specify the period within which the penalty is to be paid;
 - (d) state that the decision to require the producer to pay the penalty, and the decision as to the amount of the penalty, may be appealed under the 2000 Regulations.
- (8) The information is—
- (a) the date on which the contravention occurred,
 - (b) the amount of the daily penalty calculated in accordance with this regulation and Schedule 3 from that day up to and including the day on which the demand is made, and
 - (c) the daily rate at which the penalty continues to accrue in accordance with Schedule 3 until the producer complies with the relevant information notice or compliance notice (except to the extent that it is no longer to possible to meet a deadline because the deadline has passed).
- (9) For the purposes of calculating the final amount of the daily penalty that is due, the day on which the producer starts to comply with the relevant notice is to be disregarded.
- (10) If the producer makes an appeal to the tribunal against the decision under this regulation to require the producer to pay a daily penalty, or as to the amount of that daily penalty, in accordance with regulation 4 of the 2000 Regulations, any day falling within the appeal period is to be disregarded when determining the final amount of the penalty to be paid by the producer.
- (11) For the purposes of paragraph (10), “appeal period” means the period—
- (a) beginning with the day on which the tribunal receives the relevant notice of appeal, and
 - (b) ending with—
 - (i) the day on which the appeal is withdrawn, or
 - (ii) if the decision is upheld following the appeal, the day on which the appeal is finally determined.

Appeals

33.—(1) A UK producer has a right of appeal against a relevant enforcement decision in accordance with the 2000 Regulations.

(2) For this purpose, the 2000 Regulations apply in relation to relevant enforcement decisions as they apply to enforcement decisions (within the meaning of those Regulations) but with the modification specified in paragraph (3).

(3) The modification is that a reference to an enforcement decision is to be read as a reference to a relevant enforcement decision (within the meaning of this regulation).

(4) In this regulation “relevant enforcement decision”, in relation to a producer, means a decision of the Secretary of State—

- (a) to give the producer an information notice under regulation 25,
- (b) to give the producer a compliance notice,
- (c) to require the producer to pay a penalty under regulation 32, or
- (d) as to the amount of such a penalty.