
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.