
STATUTORY INSTRUMENTS

2018 No. 345

**The Branded Health Service
Medicines (Costs) Regulations 2018**

PART 2

MAXIMUM PRICES

Demands and appeals

17.—(1) Where a manufacturer or supplier is liable to pay a recoverable sum under regulation 14(2) the Secretary of State may make a demand for payment from the manufacturer or supplier.

(2) A demand made under paragraph (1) must be made by way of issuing a written notice to that manufacturer or supplier and must state—

- (a) the amount of the recoverable sum calculated up to the date on which the demand is made;
- (b) the date before the end of which the recoverable sum must be paid;
- (c) the daily rate at which the interest, calculated in accordance with regulation 15(2) and payable once the recoverable sum is overdue, is to accrue for as long as the recoverable sum continues to be overdue; and
- (d) the manufacturer's or supplier's appeal rights.

(3) Where a manufacturer or supplier is liable to pay a penalty under regulation 16(2) or (4), the Secretary of State may make a demand for payment of the penalty from the manufacturer or supplier.

(4) A demand made under paragraph (3) must be made by way of issuing a written notice to that manufacturer or supplier and must state—

- (a) either or both of the following—
 - (i) the amount of penalty calculated in accordance with regulation 16(2) up to the date on which the demand is made,
 - (ii) the amount of penalty determined by the Secretary of State in accordance with regulation 16(5);
- (b) the date before which the amounts referred to in sub-paragraphs (a)(i) or (ii) must be paid;
- (c) with respect to a penalty calculated in accordance with regulation 16(2) the daily rate at which the penalty continues to accrue until the maximum price that that manufacturer or supplier charges for an item of the presentation is the maximum price permitted by regulation 8;
- (d) the manufacturer's or supplier's appeal rights.

(5) If a manufacturer or supplier sends a notice of an appeal to the Tribunal in accordance with regulation 4 of the Health Service Medicines (Price Control Appeal) Regulations 2000, in respect of a demand issued by way of a notice under paragraph (2) or (4), the period beginning on the date that the notice is received by the Tribunal to the date on which the appeal is finally determined or

is withdrawn is discounted for the purposes of the calculation of the number of days in respect of which—

- (a) the recoverable sum is overdue; or
 - (b) the manufacturer or supplier supplies an item of presentation in excess of the maximum price permitted by regulation 8.
- (6) For the purposes of calculating the amount of penalty by reference to a number of days, the day on which the manufacturer or supplier charges the maximum price permitted by regulation 8 for that presentation does not count towards the calculation of that number of days.