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STATUTORY INSTRUMENTS

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**2018 No. 345**

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

**PART 2**

**MAXIMUM PRICES**

**Penalties**

**16.**—(1) Paragraph (2) applies where a manufacturer or supplier supplies an item of presentation at a price in excess of the maximum price permitted by regulation 8.

(2) Where this paragraph applies, the manufacturer or supplier is liable to pay to the Secretary of State a penalty, calculated on a daily basis in accordance with Schedule 5 read with regulation 17(5) and (6), until the maximum price that the manufacturer or supplier charges for an item of that presentation is the maximum price permitted by regulation 8.

(3) Paragraph (4) applies where a manufacturer or supplier contravenes regulation 9(2).

(4) Where this paragraph applies, the manufacturer or supplier is liable to pay to the Secretary of State a single penalty not exceeding £100,000.

(5) The level of penalty referred to in paragraph (4) is to be determined by the Secretary of State, having regard to, among other factors, the following factors—

- (a) whether the manufacturer or supplier has previously contravened regulation 8;
- (b) the total net sales income of the manufacturer or supplier;
- (c) the estimated quantity of supply of the presentation; and
- (d) the difference between the gross sales income that the manufacturer or supplier received for the supply of the presentation prior to the determination of the maximum price by the Secretary of State and the maximum price as determined by the Secretary of State.