STATUTORY INSTRUMENTS

# 2018 No. 384

# NATIONAL HEALTH SERVICE, ENGLAND AND WALES
# NATIONAL HEALTH SERVICE, SCOTLAND
# HEALTH AND PERSONAL SOCIAL SERVICES, NORTHERN IRELAND

## The Health Service Medicines (Price Control Penalties and Price Control Appeals Amendment) Regulations 2018

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| *Made - - - -* | *19th March 2018* |
| *Laid before Parliament* | *20th March 2018* |
| *Coming into force - -* | *11th April 2018* |

The Secretary of State for Health and Social Care makes the following Regulations in exercise of the powers conferred by sections 265(1), (2), (5) and (6) and 272(7) and 272(8) of the National Health Service Act 2006(**1**), having consulted in accordance with section 265(9) of that Act(**2**) the industry body(**3**) and any other body which appears to the Secretary of State appropriate to represent UK producers.

### Citation and commencement

**1.** These Regulations may be cited as the Health Service Medicines (Price Control Penalties and Price Control Appeals Amendment) Regulations 2018 and come into force on 11th April 2018.

### Section 262 of the National Health Service Act 2006: Penalties

**2.**—(1) Paragraph (2) applies where, for the supply of a health service medicine, a manufacturer or supplier charges a price in excess of the limit specified in a direction given by the Secretary of

(**1**) 2006 c.41; section 265 has been amended by the Health Service Medical Supplies (Costs) Act 2017 (c.23), sections 6(3), (4), 7(5) and 10(7) to (14). *See* section 275(1) of the National Health Service Act 2006 for the definition of "regulations" which is relevant to the powers being exercised.
(**2**) Inserted by the Health Service Medical Supplies (Costs) Act 2017, section 10(13).
(**3**) *See* section 266(6) of the National Health Service Act 2006, which contains the relevant definition of "the industry body".

State under section 262(1)(a) of the National Health Service Act 2006(**4**) (power to control prices) on or after the date on which the direction takes effect.

(2) Where this paragraph applies, the manufacturer or supplier is liable to pay to the Secretary of State a penalty, in respect of the period starting on the date which the direction takes effect, calculated on a daily basis in accordance with the Schedule read with regulations 3(3) and 4(2), until the price charged by the manufacturer or supplier for the supply of the health service medicine complies with the limit specified in the direction.

**Demands**

**3.**—(1) The Secretary of State may make a demand for payment of the penalty from a manufacturer or supplier liable to pay a penalty under regulation 2(2).

(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 penalty calculated in accordance with the Schedule up to the date on which the demand is made;

(b) the date before which the amount referred to in paragraph (a) must be paid;

(c) the daily rate at which the penalty continues to accrue until the price charged by the manufacturer or supplier for the supply of the health service medicine complies with the limit specified in the direction referred to in regulation 2(1); and

(d) the manufacturer's or supplier's appeal rights.

(3) For the purposes of calculating the amount of a penalty by reference to a number of days, the day on which the manufacturer or supplier complies with the limit specified in the direction referred to in regulation 2(1) does not count towards the calculation of the number of days.

**Appeals**

**4.**—(1) A manufacturer or supplier in respect of whom the Secretary of State has made a demand for payment of a penalty issued by way of a notice under regulation 3(2) has by virtue of this paragraph a right of appeal against that demand in accordance with the Health Service Medicines (Price Control Appeal) Regulations 2000(**5**).

(2) 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 (time for and manner of making an appeal), in respect of a demand issued by way of a notice under regulation 3(2), the period beginning on the date that notice of an appeal is received by the Tribunal to the date on which the appeal is finally determined or is withdrawn (including both dates) is discounted for the purposes of the calculation of the number of days in respect of which the manufacturer or supplier supplies the health service medicine in excess of the limit specified in the direction referred to in regulation 2(1).

**Amendment of the Health Service Medicines (Price Control Appeals) Regulations 2000**

**5.**—(1) The Health Service Medicines (Price Control Appeals) Regulations 2000 are amended as follows.

(2) In regulation 7 (appointment of tribunal) omit paragraph (9).

(3) In regulation 26 (hearing to be in public) omit paragraph (2).

(**4**) 2006 c. 41; section 262 was amended by the Health Service Medical Supplies (Costs) Act 2017, section 4. *See* section 266(1)(b) of the National Health Service Act 2006 which empowers the Secretary of State to exercise the powers under section 262(1)(a) by giving directions to a specific manufacturer or supplier.

(**5**) S.I. 2000/124 as amended by S.I. 2000/870, 2006/680 and 2007/1898.