
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations relate principally to the circumstances where, for the supply of a health service medicine, a manufacturer or supplier charges in excess of the limit specified in a direction given under section 262(1)(a) of the National Health Service Act 2006 (“NHS Act 2006”).

Regulation 2 provides that in these circumstances the manufacturer or supplier is liable to pay, on demand, a daily penalty to the Secretary of State – and the Schedule contains provisions relating to the calculation of that daily penalty.

Regulation 3 makes provision for the Secretary of State to make a demand for payment by way of issuing a notice to the manufacturer or supplier.

Regulation 4 provides the manufacturer or supplier that has been issued with a penalty notice with a right of appeal, and ensures that the period during which an appeal is ongoing is discounted for the purposes of calculating daily penalties.

The Health Service Medicines (Price Control Appeals) Regulations 2000⁽¹⁾ (“the Appeals Regulations”) make provision for the appeals process where a manufacturer, supplier or where relevant other UK producer has a right of appeal in relation to enforcement decisions made under sections 260 to section 265 of the NHS Act 2006.

Regulation 5 amends the Appeals Regulations by removing the reference to the Council of Tribunals which has been abolished.

Regulation 6 requires the Secretary of State to review the operation and effect of these Regulations and publish a report setting out the conclusions of that review a year after the commencement of these Regulations and annually after that.

⁽¹⁾ S.I. 2000/124 as amended by S.I. 2000/870, 2006/680 and 2007/1898.