
STATUTORY INSTRUMENTS

2018 No. 345

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

PART 1

PAYMENT SCHEME

Payment scheme

3.—(1) Subject to paragraph (4), the manufacturer or supplier that is responsible for the first relevant supply of an item of presentation must pay 7.80% of the net sales income received in respect of that supply to the Secretary of State in accordance with Schedule 1.

(2) Subject to paragraph (3), for these purposes the first relevant supply is the first occasion on which that item of presentation is supplied by any manufacturer or supplier having a place of business in the United Kingdom (MS1) to another person having a place of business in the United Kingdom (MS2) that is not in the same group as MS1.

(3) If MS2 is—

- (a) the marketing authorisation holder (MAH) in respect of that item of presentation; or
- (b) a manufacturer or supplier in the same group as MAH,

the first relevant supply is the next supply of that item of presentation to a person having a place of business in the United Kingdom that is not in the same group as MS2.

(4) Subject to paragraph (5), paragraph (1) does not apply to the net sales income received in respect of the supply of—

- (a) any item of presentation which was in respect of that supply, supplied under—
 - (i) a contract with a contracting authority based on a framework agreement where that framework agreement was entered into on or before the date of the coming into force of these Regulations or was entered into following a tender which closed on or before the date of the coming into force of these Regulations,
 - (ii) a public contract entered into on or before the date of the coming into force of these Regulations or was entered into following a tender which closed on or before the date of the coming into force of these Regulations;
- (b) any item of low cost presentation;
- (c) any item of parallel distributed presentation;
- (d) any item of voluntary scheme presentation.

(5) Paragraph (4)(a) does not apply to any item of presentation added to a framework agreement or public contract after the coming into force of these Regulations.

(6) This regulation does not apply to a small manufacturer or supplier.

Direction to make a payment

4.—(1) This regulation applies where the Secretary of State considers that a manufacturer or supplier has entered into an arrangement whose main purpose or one of whose main purposes is to reduce or avoid a payment in respect of a sale of any item of presentation that either that or another manufacturer or supplier would otherwise be liable to make under regulation 3.

(2) Where this regulation applies the Secretary of State may give a direction to any manufacturer or supplier that has entered into such an arrangement to do either or both of the following—

- (a) pay the amount so reduced or avoided in relation to such a sale;
- (b) pay 7.80% in respect of any future sale of any item of that presentation under that arrangement in accordance with Schedule 1.

(3) Any direction given under paragraph (2) must specify—

- (a) the reason why the Secretary of State considers that the manufacturer or supplier should pay the amount;
- (b) the reduced or avoided amount of payment that the manufacturer or supplier must pay to the Secretary of State in relation to the sale referred to in paragraph (2)(a) and the period within which it must be paid;
- (c) whether the manufacturer or supplier is required to pay 7.80% in respect of the sale referred to in paragraph (2)(b); and
- (d) the manufacturer's or supplier's appeal rights.

(4) In this regulation—

“an arrangement” includes any scheme, arrangement or understanding, whether or not legally enforceable;

“supplier” means any person who supplied any item of presentation and is not limited to circumstances where that supply is by way of sale.

(5) This regulation does not apply to a small manufacturer or supplier.

Interest payable on late payment

5.—(1) Paragraph (2) applies where—

- (a) the whole or any part of the amount required to be paid by a manufacturer or supplier under regulation 3 is not paid in accordance with table 1 of Schedule 1 and so an amount is overdue; or
- (b) the whole or any part of the amount required to be paid by a manufacturer or supplier under a direction given under regulation 4 is not paid in accordance with that direction, and so an amount is overdue.

(2) Where this paragraph applies, the manufacturer or supplier is liable to pay to the Secretary of State interest, calculated in accordance with paragraph (3) read with regulation 1(4) and 7(4), on the amount referred to in paragraph (1)(a) or (b) which is overdue until that amount is paid.

(3) The interest payable under paragraph (2) shall be simple interest calculated from day to day at a rate of 2.5 per cent per annum over the Bank of England base rate as it may be from time to time and applied to any amount outstanding on that day.

(4) For the purpose of this regulation—

the “Bank of England base rate” means—

- (a) the rate announced from time to time by the Monetary Policy Committee of the Bank of England as the official dealing rate, being the rate at which the Bank is willing to enter into transactions for providing short term liquidity in the money markets; or

- (b) where an order under section 19 of the Bank of England Act 1998(1) (reserve powers) is in force, any equivalent rate determined by the Treasury under that section.

Penalties

6.—(1) Paragraph (2) applies where—

- (a) the whole or any part of the amount required to be paid by a manufacturer or supplier under regulation 3 is not paid in accordance with table 1 of Schedule 1 and so an amount is overdue; or
- (b) the whole or any part of the amount required to be paid by a manufacturer or supplier under a direction given under regulation 4 is not paid in accordance with that direction, and so an amount is overdue.

(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 regulations 1(4) and 7(4), until the overdue amount referred to in paragraph (1)(a) or (b) is paid.

Demands and appeals

7.—(1) Paragraph (2) applies where—

- (a) the whole or any part of the amount required to be paid by a manufacturer or supplier under regulation 3 is not paid in accordance with table 1 of Schedule 1 and so an amount is overdue; or
- (b) the whole or any part of the amount required to be paid by a manufacturer or supplier under a direction given under regulation 4 is not paid in accordance with that direction, and so an amount is overdue.

(2) Where this paragraph applies the Secretary of State may make a demand for payment from the manufacturer or supplier in respect of the overdue amount.

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

- (a) the overdue amount referred to in paragraph (1)(a) or (b);
- (b) the amount of interest calculated in accordance with regulation 5(3) up to the date on which the demand is made;
- (c) the amount of penalty calculated in accordance with regulation 6(2) up to the date on which the demand is made;
- (d) the daily rate at which the interest and penalty continues to accrue for as long as the amount referred to in paragraph (1)(a) or (b) continues to be overdue; and
- (e) the manufacturer's or supplier's appeal rights.

(4) 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(2), in respect of a demand issued by way of a written notice under paragraph (3), 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 an amount referred to in paragraph (1)(a) or (b) is overdue.

(1) 1998 c. 11.

(2) S.I. 2000/124 as amended by S.I. 2000/870 and 2007/1898.