
STATUTORY INSTRUMENTS

2018 No. 345

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

PART 1

PAYMENT SCHEME

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 [^{F1}the relevant payment percentage referred to in [^{F2}regulation 3(1) ^{F3}... or (5A)]] 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 [^{F4}the relevant payment percentage referred to in [^{F5}regulation 3(1) ^{F6}... or (5A)]] 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.

Textual Amendments

- F1** Words in reg. 4(2)(b) substituted (1.1.2019) by [The Branded Health Service Medicines \(Costs\) \(Amendment\) Regulations 2018 \(S.I. 2018/1255\)](#), regs. 1, **2(4)(a)**
- F2** Words in reg. 4(2)(b) substituted (1.4.2020) by [The Branded Health Service Medicines \(Costs\) \(Amendment\) Regulations 2020 \(S.I. 2020/258\)](#), regs. 1, **2(3)(a)**
- F3** Word in reg. 4(2)(b) omitted (1.1.2024) by virtue of [The Branded Health Service Medicines \(Costs\) \(Amendment\) \(No. 2\) Regulations 2023 \(S.I. 2023/1307\)](#), regs. 1(1), **2(3)**
- F4** Words in reg. 4(3)(c) substituted (1.1.2019) by [The Branded Health Service Medicines \(Costs\) \(Amendment\) Regulations 2018 \(S.I. 2018/1255\)](#), regs. 1, **2(4)(b)**
- F5** Words in reg. 4(3)(c) substituted (1.4.2020) by [The Branded Health Service Medicines \(Costs\) \(Amendment\) Regulations 2020 \(S.I. 2020/258\)](#), regs. 1, **2(3)(b)**
- F6** Word in reg. 4(3)(c) omitted (1.1.2024) by virtue of [The Branded Health Service Medicines \(Costs\) \(Amendment\) \(No. 2\) Regulations 2023 \(S.I. 2023/1307\)](#), regs. 1(1), **2(3)**

Changes to legislation:

There are currently no known outstanding effects for the The Branded Health Service Medicines (Costs) Regulations 2018, Section 4.