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STATUTORY INSTRUMENTS

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**2018 No. 345**

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

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

*Made* - - - - - *8th March 2018*  
*Laid before Parliament* *9th March 2018*  
*Coming into force* *1st April 2018*

**THE BRANDED HEALTH SERVICE  
MEDICINES (COSTS) REGULATIONS 2018**

1. Citation, commencement and interpretation
2. Application

PART 1

PAYMENT SCHEME

3. Payment scheme
4. Direction to make a payment
5. Interest payable on late payment
6. Penalties
7. Demands and appeals

PART 2

MAXIMUM PRICES

8. Maximum price
9. New presentation
10. Temporary exemptions

*Status: This is the original version (as it was originally made).*

11. Increases
12. Decreases
13. Former voluntary scheme members
14. Recoverable sum
15. Interest payable on late payment of the recoverable sum
16. Penalties
17. Demands and appeals

### PART 3

#### INFORMATION REQUIREMENTS

18. Provision of information for payment scheme
19. New manufacturer or supplier
20. Small manufacturer or supplier
21. Sales report
22. Presentation report
23. Audited information
24. Written declaration of approval
25. Review
26. Penalties, demands and appeals

### PART 4

#### GENERAL PROVISIONS

27. Appeals
28. Revocation, saving and transitional provisions
29. Annual review  
Signature

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### SCHEDULES

#### SCHEDULE 1 — General provisions for payment scheme

1. Payment scheme requirements
2. Information requirements
3. Rules
4. Where the requirement to make a payment set out in...
5. Where the requirement to make a payment set out in...
6. Where a manufacturer or supplier changes the length of their...
7. A manufacturer's or supplier's "previous accounting reference period" means the...

#### SCHEDULE 2 — Small manufacturer or supplier

1. Determination of small manufacturer or supplier
2. The manufacturer or supplier referred to in paragraph 1(a) is...
3. The manufacturer or supplier referred to in paragraph 1(b) is...
4. Information requirements
5. A manufacturer or supplier referred to in paragraph 3 must...
6. Rules
7. The end date of the final period in the manufacturer's...
8. Where a manufacturer or supplier changes the length of their...
9. A manufacturer's or supplier's "previous accounting reference period" means the...

SCHEDULE 3 — New manufacturer or supplier

1. Information requirements
2. Where the new manufacturer or supplier is not a small...
3. Rules
4. The end date of the final period in a manufacturer's...
5. Where the requirement to make a payment set out in...
6. Where the requirement to make a payment set out in...
7. Where a manufacturer or supplier changes the length of their...
8. A manufacturer's or supplier's "previous accounting reference period" means the...

SCHEDULE 4 — Recoverable Sums

1. For the purposes of regulation 14, the recoverable sum will...
2. In respect of a contravention described in column (1) of...
3. For the purposes of this Schedule— (a) "second contravention" occurs...

SCHEDULE 5 — Penalties

1. Subject to paragraph 2, the daily penalty payable by a...
2. Where the Secretary of State is unable to reasonably determine...
3. Subject to paragraph 4, for the purposes of table 2,...
4. For the purposes of table 2, the Total United Kingdom...

Explanatory Note