#### STATUTORY INSTRUMENTS

### 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

- 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

### **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...
- A manufacturer's or supplier's "previous accounting reference period" means the...

Changes to legislation: There are currently no known outstanding effects for the The Branded Health Service Medicines (Costs) Regulations 2018. (See end of Document for details)

#### 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** 

Changes to legislation:
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