

---

STATUTORY INSTRUMENTS

---

**2018 No. 677**

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

The Health Service Products (Provision and  
Disclosure of Information) Regulations 2018

*Made - - - - 5th June 2018*

*Laid before Parliament 8th June 2018*

*Coming into force in accordance with regulation 1*

**THE HEALTH SERVICE PRODUCTS (PROVISION AND  
DISCLOSURE OF INFORMATION) REGULATIONS 2018**

PART 1

Introductory

1. Citation and commencement
2. Interpretation: general
3. Application
4. Exception: products not known to be health service products
5. Information required to be provided via an NHS England online gateway

PART 2

Quarterly information about unbranded generic health service medicines

6. Meaning of “unbranded generic health service medicine” and listing of a presentation of unbranded generic health service medicine
7. Information to be recorded and kept about supply of unbranded generic health service medicines: manufacturers and importers

**Changes to legislation:** There are currently no known outstanding effects for the The Health Service Products (Provision and Disclosure of Information) Regulations 2018. (See end of Document for details)

8. Information to be recorded and kept about supply of unbranded generic health service medicines: medicines wholesalers
9. Requirement to provide information about supply of unbranded generic health service medicines

### PART 3

#### Quarterly information about special health service medicines

10. Meaning of “special health service medicine”, “imported special health service medicine”, “made special health service medicine” and listing of a presentation of special health service medicine in a Drug Tariff
11. Information to be recorded about supply of made special health service medicines: manufacturers
12. Information to be recorded about supply of made special health service medicines: medicines wholesalers
13. Information to be recorded and kept about supply of imported special health service medicines: medicines wholesalers and importers
14. Requirement to provide information about the supply of special health service medicines

### PART 4

#### General information about supply of UK health service products

15. Categories of purchaser
16. Information to be recorded and kept about supply of imported special health service medicines: medicines wholesalers and importers
17. Information to be recorded and kept about supply of health service medicines other than imported special health service medicines: medicines wholesalers
18. Information to be recorded and kept about supply of health service medicines other than imported special health service medicines: other UK producers
19. Information to be recorded and kept about supply of health service medicines to patients otherwise than by sale
20. Information to be recorded and kept about supply of health service appliances: manufacturers and importers
21. Information to be recorded and kept about supply of listed health service appliances: medical supplies wholesalers
22. Information to be recorded and kept about supply of appliances, food and dermatological products to patients otherwise than by sale
23. Provision of information recorded and kept under this Part to the Secretary of State
24. Provision of information: small producers

### PART 5

#### Information about costs incurred in connection with the manufacturing, distribution or supply of UK health service products

25. Provision of information about costs incurred in connection with the manufacture or distribution of a particular health service medicine or appliance
26. Provision of general information about costs incurred in connection with the manufacture or distribution of health service medicines and appliances

## PART 6

### Information about price and availability of health service medicines

27. Provision of information about English health service medicines which are not available at the reimbursement price
28. Provision of information about availability of health service medicines
29. Requirement to provide information about discontinuation or anticipated supply shortage of certain health service medicines

## PART 7

### Information about reasonable estimates

30. Requirement to provide information about reasonable estimates

## PART 8

### Enforcement and appeals

31. Compliance procedure
32. Penalties
33. Appeals

## PART 9

### Disclosure of information

34. Disclosure of information

## PART 10

### Miscellaneous

35. Transitional provisions
36. Annual review  
Signature

---

### SCHEDULE 1 — Interpretation: general

1. Interpretation: general
2. Meaning of “presentation of health service medicine”
3. Meaning of “UK primary medical services provider”, “Health Service chemist” and related expressions
4. Meaning of “net NHS expenditure”, “net NHS wholesale income”, “net purchase amount” and “net sales income”
5. Meaning of “NHS framework contract”
6. Interpretation: listing of an appliance in a Drug Tariff

### SCHEDULE 2 — Small producers

1. General
2. Interpretation of Schedule 2
3. UK primary medical providers who are small producers
4. Health Service chemists who are small producers
5. NHS hospital purchasers who are small producers
6. Other UK producers who are small producers

**Changes to legislation:** There are currently no known outstanding effects for the The Health Service Products (Provision and Disclosure of Information) Regulations 2018. (See end of Document for details)

SCHEDULE 3 — Calculation of daily penalty

1. Interpretation of Schedule 3
2. Daily penalty payable by UK producers who are small producers
3. Daily penalty payable by UK producers who are not small producers

SCHEDULE 4 — Disclosure of information under section 246B of the 2006 Act:  
prescribed bodies and prescribed purposes

1. (1) The bodies specified in column 1 of Table 1,...
2. (1) The bodies specified in column 1 of Table 2...

SCHEDULE 5 — Information about supply of unbranded generic health service  
medicines or special health service medicines: transitional provisions

1. General
2. Transitional provision: information about supply of unbranded generic health service medicines
3. Circumstances in which transitional provision in paragraph 2 ceases to apply
4. Transitional provision: information about supply of special health service medicines
5. Circumstances in which transitional provision in paragraph 4 ceases to apply

Explanatory Note

**Changes to legislation:**

There are currently no known outstanding effects for the The Health Service Products (Provision and Disclosure of Information) Regulations 2018.