



# Medicines Act 1968

## CHAPTER 67

### MEDICINES ACT 1968

#### PART I

##### ADMINISTRATION

- 1 Ministers responsible for administration of Act.
- 2 Establishment of Medicines Commission.
- 2A Establishment of the Commission on Human Medicines
- 3 Functions of the Commission
- 4 Establishment of committees.
- 5 Supplementary provisions as to Commission and committees.

#### PART II

##### LICENCES AND CERTIFICATES RELATING TO MEDICINAL PRODUCTS

##### *General provisions and exemptions*

- 6 The licensing authority.
- 7 General provisions as to dealing with medicinal products.
- 8 Provisions as to manufacture and wholesale dealing.
- 9 Exemptions for doctors and dentists
- 10 Exemptions for pharmacists.
- 11 Exemption for nurses and midwives.
- 12 Exemptions in respect of herbal remedies.
- 13 Exemptions for imports.
- 14 Exemption for re-exports.
- 15 Provision for extending or modifying exemptions.
- 16 Transitional exemptions.
- 17 Termination of transitional exemptions.

*Status: Point in time view as at 22/05/2008.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 26 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

---

*Applications for, and grant and renewal of, licences*

- 18 Application for licence.
- 19 Factors relevant to determination of application for licence.
- 20 Grant or refusal of licence.
- 21 Procedure on reference to appropriate committee
- 22 Procedure in other cases.
- 22A Hearing before person appointed
- 23 Special provisions as to effect of manufacturer's licence.
- 24 Duration and renewal of licence.

*Licences of right*

- 25 Entitlement to licence of right.
- 26 Scope of licence of right in different cases.
- 27 Proceedings on application for licence of right.

*Suspension, revocation and variation of licences*

- 28 General power to suspend, revoke or vary licences.
- 29 Procedure where licensing authority propose to suspend, revoke or vary licence under s. 28.
- 30 Variation of licence on application of holder.

*Clinical trials and medicinal tests on animals*

- 31 Clinical trials.
- 32 Medicinal tests on animals.
- 33 Exemptions in respect of medicinal tests on animals.
- 34 Restrictions as to animals on which medicinal tests have been carried out.
- 35 Supplementary provisions as to clinical trials and medicinal tests on animals.
- 36 Application for, and issue of, certificate.
- 37 Transitional provisions as to clinical trials and medicinal tests on animals.
- 38 Duration and renewal of certificate.
- 39 Suspension, revocation or variation of certificate.

*Medicated animal feeding stuffs*

- 40 Medicated animal feeding stuffs.
- 41–42 .....

*Supplementary provisions*

- 43 Extension of s. 7 to certain special circumstances.
- 44 Provision of information to licensing authority.
- 45 Offences under Part II.
- 46 Special defences under s. 45.
- 47 Standard provisions for licences
- 48 Postponement of restrictions in relation to exports.
- 49 Special provisions in respect of exporting certain products.
- 49A Special provisions in respect of exporting certain products to member States

*Status: Point in time view as at 22/05/2008.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 26 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

---

- 49B Special provisions in respect of exporting certain products to EEA States
- 50 Certificates for exporters of medicinal products.

### **PART III**

#### **FURTHER PROVISIONS RELATING TO DEALINGS WITH MEDICINAL PRODUCTS**

##### *Provisions as to sale or supply of medicinal products*

- 51 General sale lists.
- 52 Sale or supply of medicinal products not on general sale list.
- 53 Sale or supply of medicinal products on general sale list.
- 54 Sale of medicinal products from automatic machines.

##### *Exemptions from sections 52 and 53*

- 55 Exemptions for doctors and dentists etc
- 56 Exemptions in respect of herbal remedies.
- 57 Power to extend or modify exemptions.

##### *Additional provisions*

- 58 Medicinal products on prescription only.
- 58A Requirement to specify certain products as prescription-only products
- 58B Requirement to specify certain products for veterinary use as prescription-only products.
- 59 Special provisions in relation to new medicinal products.
- 60 Restricted sale, supply and administration of certain medicinal products.
- 61 Special restrictions on persons to be supplied with medicinal products.
- 62 Prohibition of sale or supply, or importation, of medicinal products of specified description....
- 63 Adulteration of medicinal products.
- 64 Protection of purchasers of medicinal products.
- 65 Compliance with standards specified in monographs in certain publications.
- 66 Further powers to regulate dealings with medicinal products.

##### *Offences, and provision for disqualification*

- 67 Offences under Part III.
- 68 Disqualification on conviction of certain offences.

### **PART IV**

#### **PHARMACIES**

##### *Persons lawfully conducting retail pharmacy business*

- 69 General provisions.
- 70 Business carried on by individual pharmacist or by partners.
- 71 Bodies corporate.
- 72 Representative of pharmacist in case of death or disability.
- 72A The responsible pharmacist
- 72B Section 72A: supplementary
- 73 Power to extend or modify conditions.

*Status: Point in time view as at 22/05/2008.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 26 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

---

### *Registration of pharmacies*

- 74 Meaning of “registered pharmacy”.
- 75 Registration of premises.
- 76 Supplementary provisions as to registration of premises.
- 77 Annual return of premises to registrar.

### *Provisions as to use of certain titles, descriptions and emblems*

- 78 Restrictions on use of titles, descriptions and emblems.
- 79 Provision for modifying or extending restrictions under s. 78.

### *Disqualification, and removal of premises from register*

- 80 Power for relevant disciplinary committee to disqualify and direct removal from register.
- 81 Grounds for disqualification in certain cases.
- 82 Procedure relating to disqualification.
- 83 Revocation of disqualification.

### *Supplementary provisions*

- 84 Offences under Part IV.

## **PART V**

### CONTAINERS, PACKAGES AND IDENTIFICATION OF MEDICINAL PRODUCTS

- 85 Labelling and marking of containers and packages.
- 86 Leaflets.
- 87 Requirements as to containers.
- 88 Distinctive colours, shapes and markings of medicinal products.
- 89 Display of information on automatic machines.
- 90 Provisions as to medicated animal feeding stuffs.
- 91 Offences under Part V, and supplementary provisions.

## **PART VI**

### PROMOTION OF SALES OF MEDICINAL PRODUCTS

- 92 Scope of Part VI.
- 93 False or misleading advertisements and representations.
- 94 Advertisements requiring consent of holder of product licence.
- 95 Powers to regulate advertisements and representations.
- 96 Advertisements and representations directed to practitioners.
- 97 Power for licensing authority to require copies of advertisements.

## **PART VII**

### BRITISH PHARMACOPOEIA AND OTHER PUBLICATIONS

- 98 .....
- 99 New editions of British Pharmacopoeia, and other compendia.
- 100 Lists of names.
- 101 Other publications.
- 102 Supplementary provisions.
- 103 Construction of references to specified publications.

*Status: Point in time view as at 22/05/2008.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 26 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

---

## PART VIII

### MISCELLANEOUS AND SUPPLEMENTARY PROVISIONS

- 104 Application of Act to certain articles and substances.
- 105 Application of Act to certain other substances which are not medicinal products.
- 106 Extension of references to carrying on business.
- 107 Validity of decisions and proceedings relating thereto.
- 108 Enforcement in England and Wales.
- 109 Enforcement in Scotland.
- 110 Enforcement in Northern Ireland.
- 111 Rights of entry.
- 112 Power to inspect, take samples and seize goods and documents.
- 113 Application of sampling procedure to substance or article seized under s. 112.
- 114 Supplementary provisions as to rights of entry and related rights.
- 115 Analysis of samples in other cases.
- 115A Facilities for microbiological examinations.
- 116 Liability to forfeiture under Customs and Excise Act 1952.
- 117 Special enforcement and sampling provisions relating to animal feeding stuffs.
- 118 Restrictions on disclosure of information.
- 119 Protection for officers of enforcement authorities.
- 120 Compensation for loss of employment or loss or diminution of emoluments.
- 121 Contravention due to default of other person.
- 122 Warrant as defence.
- 123 Offences in relation to warranties and certificates of analysis.
- 124 Offences by bodies corporate.
- 125 Prosecutions.
- 126 Presumptions.
- 127 Service of documents.
- 128 Financial provisions.
- 129 Orders and regulations.
- 130 Meaning of "medicinal product" and related expressions.
- 131 Meaning of "wholesale dealing", "retail sale" and related expressions.
- 132 General interpretation provisions.
- 133 General provisions as to operation of Act.
- 134 Special provisions as to Northern Ireland.
- 135 Minor and consequential amendments and repeals.
- 136 Short title, extent and commencement.

---

## SCHEDULES

### SCHEDULE 1 — Provisions Relating to Medicines Commission and Committees

- 1 The Ministers may make provision by regulations with respect to...
- 2 The Ministers shall provide the Commission and each committee established...
- 3 The validity of any proceedings of the Commission or of...
- 4 The Commission and any such committee or sub-committee shall have...

*Status: Point in time view as at 22/05/2008.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 26 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

---

- 5 The Ministers may pay to the members of the Commission...
- 6 The Ministers shall defray any expenses incurred with their approval...
- 7 Neither the Commission nor any such committee or sub-committee shall...

#### SCHEDULE 1A — PROVISIONS RELATING TO COMMISSION AND COMMITTEES

- 1 Interpretation
- 2 Co-opted members
- 3 Expert Advisory Groups
- 4 Appointment by the Commission of Expert Advisory Groups
- 5 Delegation of functions by Advisory Bodies
- 6 Terms of office of members
- 7 Staff, premises and facilities
- 8 Validity of proceedings
- 9 Proceedings
- 10 Remuneration and expenses of members
- 11 Expenses of Advisory Bodies and Expert Advisory Groups
- 12 Status

#### SCHEDULE 2 — SUSPENSION, REVOCATION OR VARIATION OF LICENCE

##### *Procedure on consultation with appropriate committee*

- 1 Subject to paragraph 8 below, where the licensing authority propose,...
- 2 (1) Where the appropriate committee are consulted under the preceding...
- 3 (1) After receiving the report of the appropriate committee the...
- 4 If— (a) the appropriate committee was consulted under paragraph 1...
- 5 (1) Subject to sub-paragraph (4) of this paragraph, a person...

##### *Procedure in other cases*

- 6 (1) This paragraph applies where the licensing authority propose, in...

##### *Hearing before person appointed*

- 7 (1) If the holder of the licence gives notice under...

##### *Procedure in cases of urgency*

- 8 Notwithstanding anything in paragraphs 1 to 7 of this Schedule,...
- 9 If the licence is a product licence, the licensing authority...
- 10 If, after the suspension has taken effect—
- 11 (1) This paragraph applies where, in the circumstances specified in...

##### *Interpretation*

- 12 In this Schedule, the “the time allowed” means the period...

#### SCHEDULE 3 — SAMPLING

##### *Introductory*

- 1 (1) The provisions of this Schedule shall have effect where...

*Status: Point in time view as at 22/05/2008.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 26 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

---

#### *Division of sample*

- 2 The sampling officer shall forthwith divide the sample into three...
- 3 If the sample was purchased by the sampling officer, otherwise...
- 4 If the sampling officer obtained the sample from an automatic...
- 5 If the sample is of goods consigned from outside the...
- 6 If, in a case not falling within any of paragraphs...
- 7 If, in a case not falling within any of paragraphs...
- 8 In any case not falling within any of paragraphs 3...
- 9 In every case falling within any of paragraphs 3 to...
- 10 Of the remaining parts of the sample into which the...
- 11 Where a sample consists of substances or articles enclosed in...
- 12 Section 127 of this Act shall have effect in relation...
- 13 If after reasonable inquiry the sampling officer is unable to...

#### *Notice to person named on container*

- 14 (1) Where it appears to the sampling officer that a...

#### *Analysis or other examination of sample*

- 15 If the sampling officer decides to submit the sample for...
- 16 Where the relevant enforcement authority is a Minister or the...
- 17 Any such arrangements as are mentioned in paragraph 15(b) or...
- 18 (1) Subject to the following sub-paragraph, the person to whom...
- 19 (1) A public analyst who has analysed a sample submitted...
- 20 (1) Any person to whom, in accordance with paragraphs 2...

#### *Provisions as to evidence*

- 21 In any proceedings for an offence under this Act a...
- 22 In any proceedings for an offence under this Act a...
- 23 (1) If in any such proceedings before a magistrates' court...

#### *Analysis under direction of court*

- 24 (1) In any proceedings for an offence under this Act,...
- 25 The costs of any analysis or examination under paragraph 24...

#### *Proof by written statement*

- 26 In relation to England and Wales section 9 of the...

#### *Power to modify sampling provisions*

- 27 The Ministers may by order provide that, in relation to...

#### *Payment for sample taken under compulsory powers*

- 28 (1) Where a sampling officer takes a sample in the...

#### *Application of s. 64 to samples*

- 29 Where a medicinal product is taken as a sample by...

#### SCHEDULE 4 — Provisions relating to Northern Ireland

- 1 (1) The Minister of Health and Social Services for Northern...

*Status: Point in time view as at 22/05/2008.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 26 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

---

- 2 Provisions relating to Northern Ireland
- 3 Provisions relating to Northern Ireland
- 4 Provisions relating to Northern Ireland
- 5 Provisions relating to Northern Ireland
- 6 The appropriate Northern Ireland Minister may in relation to Northern...
- 7 Where an order is made by virtue of paragraph 6...
- 8 Every order or regulation under this Act made by the...
- 9 In this Schedule “the appropriate Northern Ireland Minister”—
- 10 In this Act any reference to the Minister of Health...
- 11 The Statutory Rules (Northern Ireland) Order 1979, except article 5(2)  
(a)...

SCHEDULE 5 — Amendments of Enactments of Parliament of United Kingdom.

- 1 *The Venereal Disease Act 1917 (c. 21).*
- 2, 9 . . . . .
- 10 *The Cancer Act 1939 (c. 13.)*
- 11 . . . . .
- 12 . . . . .
- 13 .
- 14, 15 . . . . .
- 16 *The Trade Descriptions Act 1968 (c. 29).*
- 17 In section 22, in subsection (2), after the words “the...

SCHEDULE 6 — Enactments of Parliament of United Kingdom Repealed.

SCHEDULE 7 —  
. . . . .

SCHEDULE 8 — Enactments of Parliament of Northern Ireland Repealed.



**Status:**

Point in time view as at 22/05/2008.

**Changes to legislation:**

Medicines Act 1968 is up to date with all changes known to be in force on or before 26 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.