



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.

Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 21 May 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) View outstanding changes

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

Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 21 May 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) View outstanding changes

- 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.
- 67A Defence to offence of contravening section 63(a) or (b): product not sold or supplied
- 67B Defence to offence of contravening section 63(a) or (b): product sold or supplied
- 67C Defence to offence of contravening section 64
- 67D Defences under sections 67A, 67B and 67C: evidence etc.
- 67E Sections 67A to 67D: “adulteration” and “registrant”
- 67F Sections 67A to 67D: “relevant pharmacy service”
- 68 Disqualification on conviction of certain offences.

PART IV

PHARMACIES

Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 21 May 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) View outstanding changes

Persons lawfully conducting retail pharmacy business

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

Registration of pharmacies

- 74 Meaning of "registered pharmacy".
- 74A Registration of premises: Great Britain
- 74B Conditions for registration: Great Britain
- 74C Supplementary provision in respect of registration of premises: Great Britain
- 74D Conditional registration: Great Britain
- 74E Supplementary provision in respect of conditional registration: Great Britain
- 74F Giving of notice by registrar: Great Britain
- 74G Voluntary removal from the register: Great Britain
- 74H (1) Subject to subsection (2), where a change occurs in...
- 74I Supplementary provision in respect of change of ownership of retail pharmacy business: Great Britain
- 74J Temporary registration with regard to emergencies involving loss of human life or human illness etc.
- 74K Temporary annotations with regard to emergencies involving loss of human life or human illness etc.
- 74L Evidence of registration: Great Britain
- 75 Registration of premises: Northern Ireland.
- 76 Supplementary provisions as to registration of premises: Northern Ireland.
- 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.
- 82A Interim measures
- 83 Revocation of disqualification.

Supplementary provisions

- 84 Offences under Part IV.
- 84A Rules by the General Pharmaceutical Council

Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 21 May 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) View outstanding changes

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 British Pharmacopoeia and Other Publications
- 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.

PART VIII

MISCELLANEOUS AND SUPPLEMENTARY PROVISIONS

- 104 Application of the 2012 Regulations to certain articles and substances.
- 105 Application of the 2012 Regulations 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 for forfeiture under Customs and Excise Act 1952.
- 117 Special enforcement and sampling provisions relating to animal feeding stuffs.

Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 21 May 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) View outstanding changes

- 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 Warranty 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...
- 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

Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 21 May 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) View outstanding changes

Procedure on consultation with appropriate committee

- 1 SUSPENSION, REVOCATION OR VARIATION OF LICENCE
- 2 SUSPENSION, REVOCATION OR VARIATION OF LICENCE
- 3 SUSPENSION, REVOCATION OR VARIATION OF LICENCE
- 4 SUSPENSION, REVOCATION OR VARIATION OF LICENCE
- 5 SUSPENSION, REVOCATION OR VARIATION OF LICENCE

Procedure in other cases

- 6 SUSPENSION, REVOCATION OR VARIATION OF LICENCE

Hearing before person appointed

- 7 SUSPENSION, REVOCATION OR VARIATION OF LICENCE

Procedure in cases of urgency

- 8 SUSPENSION, REVOCATION OR VARIATION OF LICENCE
- 9 SUSPENSION, REVOCATION OR VARIATION OF LICENCE
- 10 SUSPENSION, REVOCATION OR VARIATION OF LICENCE
- 11 SUSPENSION, REVOCATION OR VARIATION OF LICENCE

Interpretation

- 12 SUSPENSION, REVOCATION OR VARIATION OF LICENCE

SCHEDULE 3 — SAMPLING

Introductory

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

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, 4,...
- 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...

Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 21 May 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) View outstanding changes

- 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 for Health, Social Services and Public Safety...
- 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 Department 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...

Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 21 May 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) [View outstanding changes](#)

SCHEDULE 6 — Enactments of Parliament of United Kingdom Repealed.

SCHEDULE 7 —

.

SCHEDULE 8 — Enactments of Parliament of Northern Ireland Repealed.

Changes to legislation:

Medicines Act 1968 is up to date with all changes known to be in force on or before 21 May 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.

[View outstanding changes](#)

Changes and effects yet to be applied to :

- s. 10233133 amended (prosp.) by [1997 c. 19 s. 1Sch. para. 2](#)(adding1954 c 61 [s. 13A-13M](#))
- s. 52 amended (prosp.) by [1997 c. 19 s. 1Sch. para. 2](#)(adding1954 c 61 [s. 13A-13M](#))
- s. 69(1) amended (prosp.) by [1997 c. 19 s. 1Sch. para. 5\(a\)](#)
- s. 75(4)-(6) omitted by [S.I. 2016/372 art. 8](#)

Changes and effects yet to be applied to the whole Act associated Parts and Chapters:

Whole provisions yet to be inserted into this Act (including any effects on those provisions):

- s. 69(1A)(1B) added (prosp.) by [1997 c. 19 s. 1Sch. para. 5\(b\)](#)
- s. 84B inserted by [S.I. 2016/372 art. 12](#)