



Therapeutic Substances Act 1956

1956 CHAPTER 25 4 and 5 Eliz 2

An Act to consolidate the Therapeutic Substances Act 1925, and the Therapeutic Substances (Prevention of Misuse) Acts 1947 to 1953. [15th March 1956]

Modifications etc. (not altering text)

C1 Act repealed (*prosp.*) by [Medicines Act 1968 \(c. 67\)](#), s. 136(3), [Sch. 6](#)

PART I

CONTROL OF MANUFACTURE AND IMPORTATION OF CERTAIN THERAPEUTIC SUBSTANCES

1 Substances to which Part I applies.

The substances to which this Part of this Act applies are the substances specified in the First Schedule to this Act and any other therapeutic substances which may from time to time be added to that Schedule by regulations made under this Part of this Act as being substances the purity or potency of which cannot be adequately tested by chemical means.

Modifications etc. (not altering text)

C2 [S. 1](#) repealed (20.2.1976) in relation to substances in [Sch. 1](#) specified in [S.I. 1976/74](#), [art. 1\(2\)](#) and [S.R. 1976 No. 58 \(N.I.\)](#) by [Medicines Act 1968 \(c. 67\)](#), [Sch. 6](#) and [S.I. 1976/74](#), [art. 1\(1\)\(a\)](#)

2 ^{F1}

Textual Amendments

F1 [S. 2](#) repealed by [Medicines Act 1968 \(c. 67\)](#), [Sch. 6](#) and [S.I. 1976/74](#), [art. 1\(1\)\(b\)](#) and [S.R. 1976 No. 58 \(N.I.\)](#)

Status: Point in time view as at 01/02/1991.

*Changes to legislation: There are currently no known outstanding effects for the
 Therapeutic Substances Act 1956 (repealed 5.11.1993). (See end of Document for details)*

3 Restrictions on importation of substances to which Part I applies.

- (1) The importation of a substance to which this Part of this Act applies is hereby prohibited unless the substance—
- (a) is proved to the satisfaction of the licensing authority to comply with the standard of strength, quality and purity prescribed in the case of that substance, if the substance is one the manufacture of which is carried on in the United Kingdom, or, if such manufacture is not so carried on, with such standards (if any) of strength, quality and purity, as may be prescribed for that substance, or, if no such standards are so prescribed, with such standards of quality and purity as are prescribed in the case of therapeutic substances of a similar class the manufacture of which is carried on in the United Kingdom, and is consigned to a person licensed by the licensing authority to import it; or
 - (b) is consigned to a person engaged in scientific research holding a special licence to import it for the purpose of such research issued by the licensing authority.
- (2) The issue of a licence under this section shall be subject to such conditions, including conditions as to suspension and revocation, as may be prescribed.

4 The joint committee and the advisory committee.

- (1) For the purpose of framing regulations under this Part of this Act and for securing uniformity of standards, there shall be established a joint committee consisting of [^{F2}the Secretary of State for Health], who shall be chairman, [^{F3}the Secretary of State for Wales, the Secretary of State for Scotland], and the Minister of Health and Local Government for Northern Ireland:
 Provided that each member of the joint committee may appoint a deputy to act for him at meetings of the committee at which he is unable to be present.
- (2) For the purpose of assisting the joint committee in the framing of regulations under this Part of this Act, there shall be appointed an advisory committee consisting of one member appointed by [^{F2}the Secretary of State for Health], who shall be chairman, one member appointed by [^{F3}the Secretary of State for Wales and one by the Secretary of State for Scotland], one member appointed by the Minister of Health and Local Government for Northern Ireland, one member appointed by the [^{F4}National Biological Standards Board], one member appointed by the General Medical Council, one member appointed by the British Medical Association, one member appointed by the Council of the Pharmaceutical Society of Great Britain, and one member appointed by the Council of the Royal Institute of Chemistry.

Textual Amendments

- F2** Words substituted by virtue of S.I. 1988/1843, arts. 2(1), 5(4), Sch. 2 Pt. 1, **Sch. 3 para. 1(b)**
F3 Words substituted by S.I. 1969/388, **Sch. 1**
F4 Words substituted by **Biological Standards Act 1975 (c. 4), s. 6(1)**

Modifications etc. (not altering text)

- C3** Functions of Minister of Health and Local Government for Northern Ireland now exercisable by head of the Department of Health and Social Services for Northern Ireland: S.R. & O. (N.I.) 1964 No. 205, **art. 2**, 1965 No. 13 and **Northern Ireland Constitution Act 1973 (c. 36), Sch. 5 para. 7(1)**

Status: Point in time view as at 01/02/1991.

Changes to legislation: There are currently no known outstanding effects for the Therapeutic Substances Act 1956 (repealed 5.11.1993). (See end of Document for details)

5 Power to make regulations.

- (1) The joint committee, after consultation with the advisory committee, may make regulations for the following purposes:—
- (a) for prescribing the standard of strength, quality and purity of any substance to which this Part of this Act applies;
 - (b) for prescribing the tests to be used for determining whether the standard prescribed as aforesaid has been attained;
 - (c) for prescribing units of standardisation;
 - (d) for adding to the First Schedule to this Act any therapeutic substance the purity or potency of which cannot be adequately tested by chemical means;
 - (e) for prescribing the form of licences under this Part of this Act and of applications therefor, and of notices to be given in connection therewith;
 - (f) for prescribing the conditions subject to which licences may be issued, including, in the case of a licence to manufacture, conditions that the licensee shall allow any inspector authorised by the licensing authority in that behalf to enter any premises where the manufacture is carried on, and to inspect the premises and plant and the process of manufacture and the means employed for standardising and testing the manufactured substance and to take samples thereof;
 - (g) for excluding from the operation of this Part of this Act, or of any of the provisions thereof, any substance intended to be used solely for veterinary purposes;
 - (h) for prescribing any other matter which under this Part of this Act is to be prescribed.
- (2) Regulations so made may also, as respects any such substance to which this Part of this Act applies as may be specified in the regulations, contain provisions—
- (a) requiring that, if advertised or sold as a proprietary medicine or contained in such a medicine, such accepted scientific name, or name descriptive of the true nature and origin of the substance, as may be prescribed shall appear on the label;
 - (b) requiring that the date of the manufacture shall be stated in the prescribed manner on all vessels or other packages in which the substance is sold or offered for sale, and prohibiting the sale of the substance after the expiration of the prescribed period from the date of manufacture;
 - (c) prohibiting the sale or the offering for sale of the substance otherwise than in a vessel or other container of such character as may be prescribed, and requiring that the prescribed label or other description shall be affixed to the vessel or other container in which the substance is sold or offered for sale.

Modifications etc. (not altering text)

- C4** Functions of the Secretary of State for Social Services under s. 5 transferred to the Secretary of State for Health by virtue of [S.I. 1988/1843](#), art. 2(1), [Sch. 2 Pt. I](#)

6 Offences under Part I.

A person who—

Status: Point in time view as at 01/02/1991.

*Changes to legislation: There are currently no known outstanding effects for the
 Therapeutic Substances Act 1956 (repealed 5.11.1993). (See end of Document for details)*

- (a) being a person who is required by this Part of this Act to be licensed in that behalf manufactures for sale a substance to which this Part of this Act applies without a licence for the purpose, or elsewhere than on premises in respect of which a licence is in force;
- (b) contravenes or fails to comply with a condition subject to which a licence under this Part of this Act is issued;
- (c) sells or has in his possession for sale a substance to which this Part of this Act applies knowing it to have been manufactured or imported in contravention of this Part of this Act or the regulations made thereunder;
- (d) contravenes or fails to comply with the provisions of any regulation made under this Part of this Act;

shall be guilty of an offence under this Part of this Act and liable, on summary conviction, to a fine not exceeding [^{F5}one hundred pounds][^{F5}level 3 on the standard scale]or, in the case of a second or subsequent conviction, to such a fine or to imprisonment for a term not exceeding three months, and in either case to forfeit any goods in connection with which the offence was committed, and without prejudice, if the offender is the holder of a licence, to the power of the licensing authority to revoke or suspend the licence.

Textual Amendments

- F5** Words “level 3 on the standard scale” substituted (S.) for words “one hundred pounds” by virtue of [Criminal Procedure \(Scotland\) Act 1975 \(c.21, SIF 39:1\)](#), **ss. 289E–289G**

Modifications etc. (not altering text)

- C5** [Criminal Procedure \(Scotland\) Act 1975 \(c.21, SIF 39:1\)](#), **s. 289E** (in relation to liability on first and subsequent convictions), applies (S.)
- C6** [Criminal Justice Act 1982 \(c.48, SIF 39:1\)](#), **ss. 35** (in relation to liability on first and subsequent convictions), 38 (increase of fines) and 46 (substitution of references to levels on the standard scale) apply (E.W.) and [S.I. 1984/703 \(N.I. 3\)](#), **arts. 5** (substitution of references to levels on the standard scale) 6 (increase of fines) and 9 (in relation to liability on first and subsequent convictions) apply (N.I.)

7 Licensing authority for purposes of Part I.

The following authorities shall be the licensing authorities for the purposes of this Part of this Act:—

- (a) as respects England and Wales, the [^{F6}Secretary of State];
- (b) as respects Scotland, the Secretary of State;
- (c) as respects Northern Ireland, the Minister of Health and Local Government for Northern Ireland.

Textual Amendments

- F6** Words substituted by virtue of [S.I. 1968/1699](#), **arts. 2, 5(4)(a)**

Status: Point in time view as at 01/02/1991.

Changes to legislation: There are currently no known outstanding effects for the Therapeutic Substances Act 1956 (repealed 5.11.1993). (See end of Document for details)

Modifications etc. (not altering text)

- C7** Functions of Minister of Health and Local Government for Northern Ireland now exercisable by head of the Department of Health and Social Services for Northern Ireland: S.R. & O. (N.I.) 1964 No. 205, [art. 2](#), 1965 No. 13 and [Northern Ireland Constitution Act 1973 \(c. 36\)](#), [Sch. 5 para. 7\(1\)](#)

PART II

8—15. ^{F7}

Textual Amendments

- F7** Ss. 8–15 repealed by [Medicines Act 1968 \(c. 67\)](#), [Sch. 6](#) and [S.I. 1977/2128](#)

PART III

GENERAL

16 Application of Statutory Instruments Act 1946, to regulations.

Any power conferred by this Act to make regulations shall be exercisable by statutory instrument which shall be subject to annulment in pursuance of a resolution of either House of Parliament.

17
(1) ^{F8}
(3) ^{F9}

Textual Amendments

- F8** S. 17(1)(2) repealed by [Northern Ireland Act 1962 \(c. 30\)](#), [Schs. 1, 4 Pt. IV](#)
F9 S. 17(3) repealed by [Northern Ireland Constitution Act 1973 \(c. 36\)](#), [Sch. 6 Pt. I](#)

18 Repeal and savings.

- (1) The enactments specified in the first and second columns of the Second Schedule to this Act are hereby repealed to the extent specified in the third column of that Schedule.
- (2) In so far as any regulation made, or having effect as if made, licence issued or other thing done under an enactment repealed by this Act could have been made, issued or done under a corresponding provision of this Act, it shall not be invalidated by the repeal effected by the foregoing subsection but shall have effect as if it had been made, issued or done under that corresponding provision.
- (3) Any document referring to an Act or enactment repealed by this Act shall be construed as referring to this Act or the corresponding enactment therein.

Status: Point in time view as at 01/02/1991.

Changes to legislation: There are currently no known outstanding effects for the Therapeutic Substances Act 1956 (repealed 5.11.1993). (See end of Document for details)

- (4) For the purpose of determining the punishment which may be imposed on a person in respect of an offence under any provision of this Act, an offence committed by him under the corresponding provision of an enactment repealed by this Act shall be deemed to have been committed under the first-mentioned provision.
- (5) The mention of particular matters in this section shall be without prejudice to the general application of [F10 sections 16(1) and 17(2)(a) of the M1 Interpretation Act 1978] with regard to the effect of repeals.

Textual Amendments

F10 Words substituted by virtue of [Interpretation Act 1978 \(c. 30\), s. 25\(2\)](#)

Modifications etc. (not altering text)

C8 The text of S. 18(1), Sch. 2 is in the form in which it was originally enacted: it was not reproduced in Statutes in Force and does not reflect any amendments or repeals which may have been made prior to 1.2.1991.

Marginal Citations

M1 [1978 c. 30.](#)

19 Short title and commencement.

- (1) This Act may be cited as the Therapeutic Substances Act 1956.
- (2) This Act shall come into operation at the expiration of one month beginning with the date of its passing.

Status: Point in time view as at 01/02/1991.

Changes to legislation: There are currently no known outstanding effects for the Therapeutic Substances Act 1956 (repealed 5.11.1993). (See end of Document for details)

SCHEDULES

FIRST SCHEDULE

Sections 1, 5.

SUBSTANCES TO WHICH PART I OF THIS ACT APPLIES

- 1 The substances commonly known as vaccines, sera, toxins, antitoxins and antigens.
- 2 Arsphenamine and analogous substances used for the specific treatment of infective disease.
- 3 Preparations of the specific antidiabetic principle of the pancreas, known as insulin.
- 4 Preparations of the posterior lobe of the pituitary body intended for use by injection.

SECOND SCHEDULE

Section 18.

ENACTMENTS REPEALED.

Modifications etc. (not altering text)

- C9** The text of S. 18(1), Sch. 2 is in the form in which it was originally enacted: it was not reproduced in Statutes in Force and does not reflect any amendments or repeals which may have been made prior to 1.2.1991.

Section 18.			SECOND SCHEDULE ENACTMENTS REPEALED	
Session and Chapter	Short Title	Extent of Repeal		
15 & 16 Geo. 5. c. 60.	The Therapeutic Substances Act, 1925.	The whole Act.		
10 & 11 Geo. 6. c. 29.	The Penicillin Act, 1947	The whole Act.		
11 & 12 Geo. 6. c. 52.	The Veterinary Surgeons Act, 1948.	In section twenty-three, the words " and (c) section one of the Penicillin Act, 1947 " in the Second Schedule, paragraph 5.		
14 & 15 Geo. 6. c. 13.	The Penicillin (Merchant Ships) Act, 1951.	The whole Act.		
1 & 2 Eliz. 2. c. 52.	The Therapeutic Substances (Prevention of Misuse) Act, 1953.	The whole Act.		
—*—				
Table of Statutes referred to in this Act				
Short Title		Session and Chapter		
Pharmacy Act, 1852	...	15 & 16 Vict. c. 56.		
Veterinary Surgeons Act, 1881	...	44 & 45 Vict. c. 62.		
Interpretation Act, 1889	...	52 & 53 Vict. c. 63.		
Merchant Shipping Act, 1894	...	57 & 58 Vict. c. 69.		
Government of Ireland Act, 1920	...	10 & 11 Geo. 5. c. 67.		
Therapeutic Substances Act, 1925	...	15 & 16 Geo. 5. c. 60.		
Pharmacy and Poisons Act, 1933	...	23 & 24 Geo. 5. c. 25.		
Veterinary Surgeons Act, 1948	...	11 & 12 Geo. 6. c. 52.		
Pharmacy Act, 1954	...	2 & 3 Eliz. 2. c. 61.		

Status:

Point in time view as at 01/02/1991.

Changes to legislation:

There are currently no known outstanding effects for the Therapeutic Substances Act 1956 (repealed 5.11.1993).