Therapeutic Substances Act 1956

1956 CHAPTER 25

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.

2 Restrictions on manufacture of substances to which Part I applies

(1) No person shall manufacture for sale a substance to which this Part of this Act applies unless he holds a licence for the purpose from the licensing authority, or elsewhere than on the premises in respect of which such a licence is in force.

(2) A licence under this section shall continue in force for such period as may be prescribed, but may from time to time be renewed for a like period, and may extend to all the substances to which this Part of this Act applies, or to such one or more of them as may be specified in the licence, and shall be issued subject to such conditions as may be prescribed.

(3) An applicant for a licence or the renewal of a licence must satisfy the licensing authority that the conditions under which the substances are to be manufactured by him and the premises in which they are to be manufactured are such as to comply with any regulations made under this Part of this Act, and an applicant who so satisfies the licensing authority shall be entitled to the grant or renewal of the licence.

(4) The licensing authority may revoke a licence or suspend it for such period as he thinks fit if, in his opinion, the licensee has failed to comply with the conditions subject to which the licence was issued or with the regulations made under this Part of this Act as to the prescribed standards of strength, quality and purity, and such revocation or

suspension may apply to all the substances to which the licence applies or to some one or more of them:

Provided that a person who is aggrieved by the revocation or suspension of his licence may appeal to the High Court, whose decision shall be final.

(5) Nothing in this section shall apply to the preparation by a duly qualified medical practitioner for any of his own patients or for and at the request of another such practitioner of a substance to which this Part of this Act applies, if it is specially prepared with reference to the condition, and for the use, of an individual patient.

(6) In the application of this section to Scotland, for the reference to the High Court there shall be substituted a reference to the Court of Session.

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 the Minister of Health, who shall be chairman, the Secretary of State, 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 the Minister of Health, who shall be chairman, one member appointed by the Secretary of State, one member appointed by the Minister of Health and Local Government for Northern Ireland, one member appointed by the Medical Research Council, 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.

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 sub stance 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.

6 Offences under Part I

A person who—

(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 one hundred pounds 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.

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 Minister of Health;

(b) as respects Scotland, the Secretary of State ;

(c) as respects Northern Ireland, the Minister of Health and Local Government for Northern Ireland.

PART II

CONTROL OF SALE, SUPPLY, DISPENSING AND ADMINISTRATION OF PENICILLIN AND CERTAIN OTHER SUBSTANCES

8 Substances to which Part II applies

(1) The substances to which this Part of this Act applies are penicillin and such other therapeutic substances as may be prescribed by regulations made by the Minister of Health, the Secretary of State and the Minister of Health and Local Government for Northern Ireland, jointly, after consultation with the Medical Research Council, being substances appearing to those Ministers to be capable of causing danger to the health of the community if used without proper safeguards.

(2) In this section " penicillin " has the meaning assigned to it by regulations for the time being in force under Part I of this Act.

9 Control of sale and supply of substances to which Part II applies

(1) Subject to the provisions of subsection (2) of this section, no person shall sell or otherwise supply a substance to which this Part of this Act applies or any preparation of which any such substance is an ingredient or part unless—

(a) he is a duly qualified medical practitioner, a registered dental practitioner or a registered veterinary surgeon or registered veterinary practitioner, or a person acting in accordance with the directions of any such practitioner or surgeon, and the substance or preparation is sold or supplied for the purposes of treatment by or in accordance with the directions of that practitioner or surgeon; or

(b) he is a registered pharmaceutical chemist or an authorised seller of poisons, and the substance or preparation is sold or supplied under the authority of a prescription signed and dated by such a practitioner or surgeon as aforesaid.

(2) The foregoing subsection shall not apply to the sale or supply of any such substance or preparation as aforesaid—

(a) by way of wholesale dealing ;

(b) for the purpose of being exported ;

(c) to any such practitioner or surgeon as aforesaid ;

(d) to any authority or person carrying on a hospital, clinic, nursing home or other institution providing medical, surgical, dental or veterinary treatment;

(e) to the owner or master of a medical store-carrying ship, for use on board the ship ;

(f) to any person carrying on an institution or business which has among its recognised activities the conduct of scientific education or research, for use by persons engaged in that education or research; or

(g) to a Minister of the Crown or Government department;

or to the sale or supply of any such substance or preparation as aforesaid as may be specified in regulations under this section if it is sold or supplied in such circumstances and in accordance with such conditions as may be so specified.

(3) The power of making regulations under this section shall be exercisable by the Minister of Health, the Secretary of State and the Minister of Health and Local Government for Northern Ireland, jointly, after consultation with the Medical Research Council and, in the case of regulations appearing to those Ministers to concern agricultural matters, with the Agricultural Research Council.

10 Control of dispensing of substances to which Part II applies

A prescription signed by a duly qualified medical practitioner, a registered dental practitioner or a registered veterinary surgeon or registered veterinary practitioner authorising the sale or supply of a substance to which this Part of this Act applies or a preparation of which any such substance is an ingredient or part shall not, subject as hereinafter provided, be dispensed on more than one occasion or more than three months after the date on which it was signed:

Provided that, if the prescription expressly directs that it may be dispensed on a specified number of occasions or at specified intervals in a specified period, it may be dispensed in accordance with that direction.

11 Control of administration of substances to which Part II applies

(1) Subject to the provisions of subsection (2) of this section, no person shall administer by way of treatment a substance to which this Part of this Act applies or a preparation of which any such substance is an ingredient or part unless he is a duly qualified medical practitioner, a registered dental practitioner or a registered veterinary surgeon or registered veterinary practitioner, or a person acting in accordance with the directions of such a practitioner or surgeon.

(2) On board a medical store-carrying ship, being a ship which does not carry on board as part of her complement a duly qualified medical practitioner, the master or a person authorised by the master in that behalf may, in accordance with any applicable

instructions contained in a book of instructions kept on board in pursuance of section two hundred of the Merchant Shipping Act, 1894, administer by way of treatment a substance to which this Part of this Act applies or a preparation of which any such substance is an ingredient or part, and the foregoing subsection shall not apply in such a case.

12 Offences under Part II

(1) A person who contravenes any of the foregoing provisions of 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 one hundred pounds or, in the case of a second or subsequent conviction, to such a fine or to imprisonment for a term not exceeding three months, or to both such fine and such imprisonment.

(2) Where an offence under this Part of this Act has been committed by a body corporate, every person who at the time of the commission of the offence was a director, general manager, secretary or other similar officer of the body corporate, or was purporting to act in any such capacity, shall be deemed to be guilty of that offence unless he proves that the offence was committed without his consent or connivance and that he exercised all such diligence to prevent the commission of the offence as he ought to have exercised having regard to the nature of his functions in that capacity and to all the circumstances.

13 Enforcement by Pharmaceutical Society

The Pharmaceutical Society of Great Britain shall have power to enforce the provisions of this Part of this Act, and for that purpose may employ the inspectors appointed by them under section twenty-five of the Pharmacy and Poisons Act, 1933, but nothing in this section shall be construed as authorising the Society to institute proceedings in Scotland for any offence under this Part of this Act.

14 Interpretation of Part II

In this Part of this Act, unless the context otherwise requires, the following expressions have the meanings hereby respectively assigned to them, that is to say:—

" authorised seller of poisons " has the meaning assigned to it by the Pharmacy and Poisons Act, 1933 ;

" master " has the same meaning as in the Merchant Shipping Act, 1894;

" medical store-carrying ship " means a ship on board which a supply of medicine and medical stores is required to be kept under section two hundred of the Merchant Shipping Act, 1894;

" registered dental practitioner " means a person registered in the dentists register under the Dentists Acts, 1878 to 1923;

" registered pharmaceutical chemist " means a person registered in the register of pharmaceutical chemists established in pursuance of the Pharmacy Act, 1852, and maintained in pursuance of subsection (1) of section two of the Pharmacy Act, 1954 ;

" registered veterinary practitioner " means a person registered in the Supplementary Veterinary Register in pursuance of the Veterinary Surgeons Act, 1948 ;

" registered veterinary surgeon " means a person registered in the register of veterinary surgeons in pursuance of the Veterinary Surgeons Act, 1881 ;

" sale by way of wholesale dealing " means sale to a person who buys for the purpose of selling again.

15 Application of Part II to Northern Ireland

(1) In the application of this Part of this Act to Northern Ireland, the following expressions have the meanings hereby respectively assigned to them, that is to say:—

" authorised seller of poisons " has the meaning assigned to it by the Medicines, Pharmacy and Poisons Act (Northern Ireland), 1945, as amended by any other enactment of the Parliament of Northern Ireland ;

" registered pharmaceutical chemist " means a person registered in the register of pharmaceutical chemists in pursuance of the Pharmacy and Poisons Acts (Northern Ireland), 1925 and 1945, or any enactment of the Parliament of Northern Ireland amending those Acts.

(2) The Ministry of Home Affairs for Northern Ireland shall have power to enforce the provisions of this Part of this Act in Northern Ireland, and for that purpose may employ the inspector appointed by the Ministry under section eight of the Pharmacy and Poisons Act (Northern Ireland), 1925.

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 General provisions as to Northern Ireland

(1) In the application of this Act to Northern Ireland, the expression "summary conviction" means conviction in accordance with the enactments (including enactments of the Parliament of Northern Ireland) for the time being in force in Northern Ireland relating to summary jurisdiction.

(2) Rules may be made under section sixty-one of the Supreme Court of Judicature Act (Ireland), 1877, as in force in Northern Ireland, regulating the practice, procedure and costs of appeals under the proviso to subsection (4) of section two of this Act.

(3) For the purposes of section six of the Government of Ireland Act, 1920, this Act shall be deemed to be an Act passed before the day appointed for the purposes of that section, but nothing in this section shall be construed as extending the legislative powers of the Parliament of Northern Ireland under section four of that Act.

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.

(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 subsection (2) of section thirty-eight of the Interpretation Act, 1889, with regard to the effect of repeals.

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.