BILLE SUBSTAINTI ICE, 1932.
THERAPEUTIC SUBSTANCES BILL, 1932.

Mar do tugadh isteach.
As introduced.

ARRANGEMENT OF SECTIONS.

[No. 26 of 1932.]

SAORSTÁT EIREANN.

BILLE SUBSTAINTI ICE, 1932.
THERAPEUTIC SUBSTANCES BILL, 1932.

BILL

entitled

AN ACT TO REGULATE THE MANUFACTURE, IMPORT AND SALE OF THERAPEUTIC (INCLUDING PROPHYLACTIC AND DIAGNOSTIC) SUBSTANCES.

BE IT ENACTED BY THE OIREACHTAS OF SAORSTÁT EIREANN AS FOLLOWS:—

Definitions.

1.—In this Act—
the expression "the Minister" means the Minister for Local Government and Public Health;
the expression "prescribed" means prescribed by regulations made by the Minister under this Act;
the expression "therapeutic" includes prophylactic and diagnostic.

Advisory Committee.

2.—(1) For the purpose of advising and assisting the Minister in the making of orders and regulations under this Act there shall be established a committee to be called and known as the Therapeutic Substances Advisory Committee (in this Act referred to as the Advisory Committee).

(2) The Advisory Committee shall consist of ten members appointed from time to time as follows, that is to say:—

(*a*) one shall be appointed by the Minister for Local Government and Public Health;

(*b*) one shall be appointed by the Minister for Agriculture, and

(*c*) one shall be appointed by each of the following bodies, that is to say, the University of Dublin, the National University of Ireland, the Medical Registration Council, the Royal College of Physicians of Ireland, the Irish Medical Association, the Veterinary Council, the Pharmaceutical Society of Ireland, and the Institute of Chemists.

(3) Every member of the Advisory Committee shall, unless he previously dies or resigns hold office for a period of three years from the date of his appointment, but shall be eligible for re-appointment.

(4) Subject to the provisions of this section, the Minister may by rules made under this section regulate the times of appointment of members of the Advisory Committee, the time and mode of filling casual vacancies in the Advisory Committee, the period of office of persons appointed to fill such vacancies, the quorum at meetings of the Advisory Committee, and the procedure of the Advisory Committee.

(5) The Advisory Committee shall meet whenever summoned by the Minister.

(6) Subject to rules made by the Minister under this section the Advisory Committee shall regulate their proceedings in such manner as they think fit.

Therapeutic substances to which Act applies.

3.—(1) This Act applies to—

(*a*) every therapeutic substance specified in the Schedule to this Act;

(*b*) such other therapeutic substances as may from time to time be declared by order for the time being in force made under this section to be therapeutic substances to which this Act applies.

(2) The Minister may, after consultation with the Advisory Committee, by order made under this section—

(*a*) declare any therapeutic substance, the purity or potency of which cannot in the opinion of the Minister be adequately tested by chemical means, to be a therapeutic substance to which this Act applies;

(*b*) revoke any order previously made by him under this section.

(3) Every order made by the Minister under this section shall be laid before each House of the Oireachtas as soon as may be after it is made, and if either such House shall, within twenty-one days on which such House has sat after such order is laid before it, pass a resolution annulling such order, such order shall be annulled accordingly but without prejudice to the validity of anything previously done thereunder.

Regulations as to standards of therapeutic substances.

4.—The Minister may, after consultation with the Advisory Committee, by order make regulations (in this Act referred to as regulations as to the standards of therapeutic substances) in relation to the following matters, that is to say:—

(*a*) the standard of strength, quality and purity of any therapeutic substance to which this Act applies;

(*b*) the tests to be used for determining whether such standard has been attained;

(*c*) units of standardisation.

General regulations.

5.—(1) The Minister may, after consultation with the Advisory Committee, by order make regulations prescribing any matter or thing which is referred to in this Act as prescribed or to be prescribed.

(2) Any regulations made by the Minister under this Act may relate to the several matters in respect of which the power to make regulations is conferred by different sections of this Act.

(3) Every regulation made under this Act shall be laid before each House of the Oireachtas as soon as may be after it is made, and if either such House shall, within twenty-one days on which such House has sat after such regulation is laid before it, pass a resolution annulling such regulation, such regulation shall be annulled accordingly but without prejudice to the validity of anything previously done thereunder.

Manufacturer's licences.

6.—(1) The Minister may grant a licence (in this Act referred to as a manufacturer's licence) to manufacture for sale any therapeutic substance to which this Act applies on the premises specified in such licence to any person who—

(*a*) applies in the prescribed form and manner to the Minister for such licence; and

(*b*) satisfies the Minister that the conditions under which such therapeutic substance is to be manufactured by him and the premises on which such substance is to be manufactured are such as to comply with any regulations made under this Act prescribing the conditions subject to which such licence is to be granted.

(2) Every manufacturer's licence shall—

(*a*) be in the prescribed form, and

(*b*) be expressed and operate to licence the person to whom it is granted to manufacture for sale all the therapeutic substances to which this Act applies or such one or more of them as may be specified in such licence on the premises specified in such licence, and

(*c*) be granted subject to the conditions prescribed in respect thereof.

(3) Every manufacturer's licence shall, unless sooner revoked or suspended under this Act, remain in force for the prescribed period from the date thereof and shall then expire.

Prohibition of manufacture of therapeutic substances without licence.

7.—(1) Subject to the provisions of this section, it shall not be lawful—

(*a*) for any person to manufacture for sale any therapeutic substance to which this Act applies unless such person holds a manufacturer's licence for the time being in force to manufacture for sale such therapeutic substance, or

(*b*) for any person to whom a manufacturer's licence has been granted to manufacture for sale any therapeutic substance elsewhere than on the premises specified in such licence.

(2) Every person who acts in contravention of this section shall be guilty of an offence under this Act.

(3) This section shall not apply to—

(*a*) the preparation by a registered medical practitioner for any of his own patients or for and at the request of another such practitioner of a therapeutic substance to which this Act applies, if it is specially prepared with reference to the condition, and for the use, of an individual patient, or

(*b*) the preparation by a registered veterinary surgeon for any animals under his care or for and at the request of another such surgeon of a therapeutic substance to which this Act applies, if it is specially prepared with reference to the condition, and for the use, of an individual animal.

Prohibition of manufacture of therapeutic substances not complying with standards of strength, purity, etc.

8.—(1) It shall not be lawful for a person to whom a manufacturer's licence has been granted to manufacture for sale any therapeutic substance to which this Act applies unless such therapeutic substance complies with the standards of strength, quality and purity prescribed in respect of such therapeutic substance by the regulations as to the standards of therapeutic substances.

(2) Every person who acts in contravention of this section shall be guilty of an offence under this Act.

Import licences.

9.—(1) The Minister may grant a licence (in this Act referred to as an import licence) to import any therapeutic substance to which this Act applies manufactured by a manufacturer specified in such licence to any person who—

(*a*) applies in the prescribed form and manner to the Minister for such licence, and

(*b*) sends with such application a written undertaking (in this Act referred to as a manufacturer's undertaking) signed by or on behalf of such manufacturer that he will, in the event of such licence being granted, during the continuance of such licence comply with the prescribed conditions.

(2) Every import licence shall—

(*a*) be in the prescribed form, and

(*b*) be expressed and operate to licence the person to whom it is granted to import from the manufacturer named therein all the therapeutic substances to which this Act applies or such one or more of them as may be specified in such licence, and

(*c*) be granted subject to the conditions prescribed in respect thereof, and

(*d*) be granted subject to the observance by such manufacturer of the manufacturer's undertaking signed by him in respect of such licence.

(3) Every import licence shall, unless sooner revoked or suspended under this Act, remain in force for the prescribed period from the date thereof and shall then expire.

10.—(1) The Minister may grant a licence (in this Act referred to as a research licence) to import any therapeutic substance to which this Act applies to any person who— **Research licences.**

(*a*) is engaged in scientific research, and

(*b*) applies in the prescribed form and manner to the Minister for such licence, and

(*c*) sends with such application a recommendation supporting such application signed by such persons as may be prescribed.

(2) Every research licence shall—

(*a*) be in the prescribed form;

(*b*) be expressed and operate to licence the person to whom it is granted to import therapeutic substances to which this Act applies or such one or more of them as may be specified in such licence;

(*c*) be granted subject to the conditions prescribed in respect thereof.

(3) Every research licence shall, unless sooner revoked or suspended under this Act, remain in force for the prescribed period from the date thereof and shall then expire.

11.—(1) It shall not be lawful to import into Saorstát Eireann any therapeutic substance to which this Act applies unless— **Restriction on import of therapeutic substances.**

(*a*) such substance is consigned to a person who is the holder of a research licence for the time being in force to import such substance, or

(*b*) such substance is consigned to a person who is the holder of an import licence for the time being in force to import such substance and such substance is imported from the manufacturer specified in such licence.

(2) Every person who acts in contravention of this section shall be guilty of an offence under this Act.

12.—Articles prohibited to be imported by virtue of this Act shall be deemed to be included among the goods enumerated and described in the Table of Prohibitions and Restrictions Inwards contained in Section 42 of the Customs Consolidation Act, 1876, and the provisions of that Act, as amended or extended by any subsequent Act, applying to the importation of prohibited or restricted goods, shall apply accordingly. **Application of Customs Acts.**

13.—(1) There shall be paid to the Minister on the grant of any licence under this Act such fee as may be fixed by the Minister, with the consent of the Minister for Finance, by regulations made under this section and different fees may be fixed in respect of different classes of licences. **Fees on grant of licences.**

(2) All fees received by the Minister under this section shall be paid into or disposed of for the benefit of the Exchequer in such manner as the Minister for Finance may direct.

14.—(1) Where a person who is the holder of a licence granted under this Act is convicted of an offence under this Act, the Minister may revoke or suspend for such period as he thinks fit, the licence or all the licences held by such person. **Revocation and suspension of licences.**

(2) Where a person is the holder of an import licence and there has in the opinion of the Minister been a breach of the manufacturer's undertaking given by the manufacturer specified in such licence, the Minister may revoke or suspend for such period as he thinks fit such licence.

(3) Where a licence is suspended under this section, such licence shall so long as such suspension continues cease to be in force.

15.—(1) An inspector shall be entitled at all reasonable times to enter any premises specified in a manufacturer's licence and to inspect such premises and the plant and the process of manufacture and the means employed for standardising and testing the therapeutic substances manufactured thereon and to take samples thereof. **Powers of inspectors.**

(2) An inspector shall be entitled at all reasonable times to enter any premises where any therapeutic substance imported under an import licence is stocked and to inspect the premises and the means (if any) employed for testing such substance and to take samples thereof.

(3) An inspector shall be entitled at all reasonable times to enter any premises where a person who is the holder of a research licence keeps any therapeutic substances and inspect such premises and investigate the manner in which the substances are used and to take samples thereof.

(4) If any person obstructs or impedes an inspector in the exercise of any of the powers conferred on an inspector under this section, he shall be guilty of an offence under this Act.

(5) In this section the expression "inspector" means a person authorised in writing by the Minister to exercise the powers conferred on an inspector by this section.

Breach of licence conditions.

16.—If any person, being the holder of a licence granted under this Act, contravenes or fails to comply with the conditions subject to which such licence was granted, such person shall be guilty of an offence under this Act.

Sale of proprietary medicine consisting of or containing therapeutic substances.

17.—The Minister may after consultation with the Advisory Committee, by order make regulations in relation to all or any of the following matters, that is to say:—

(*a*) requiring that, if any therapeutic substance to which this Act applies is advertised or sold as a proprietary medicine or is contained in a medicine so advertised or sold, such accepted scientific name or name descriptive of the true nature and origin of the substance as may be specified in such regulations shall appear on the label;

(*b*) requiring that the date of the manufacture of any therapeutic substance to which this Act applies shall be stated in the manner prescribed by such regulations on all vessels or other packages in which such substance is sold or offered for sale, and prohibiting the sale of such substance after the expiration of the period specified in such regulations from the date of manufacture;

(*c*) prohibiting the sale or offering for sale of any therapeutic substance to which this Act applies otherwise than in a vessel or other container of such character as may be specified in such regulations and requiring that the label or other description specified in such regulations shall be affixed to such vessel or container.

(2) If any person contravenes or fails to comply with any regulations made under this section he shall be guilty of an offence under this Act.

Sale of therapeutic substances unlawfully manufactured or imported.

18.—If any person sells or has in his possession for sale any therapeutic substance to which this Act applies knowing it to have been manufactured or imported in contravention of this Act or any regulations made thereunder, such person shall be guilty of an offence under this Act.

Penalty for offences.

19.—Every person guilty of an offence under this Act shall be liable on summary conviction thereof to a fine not exceeding one hundred pounds and in the case of a second or any subsequent offence, to such fine or to imprisonment with or without hard labour for any term not exceeding three months, and in either case to forfeit any goods in connection with which the offence was committed.

Expenses.

20.—Any expenses incurred in carrying this Act into execution shall, to such extent as may be sanctioned by the Minister for Finance, be paid out of moneys provided by the Oireachtas.

21.—(1) This Act may be cited as the Therapeutic Substances Act, 1932. Short title and commencement.

(2) This Act shall come into operation on such day as shall be fixed for that purpose by order of the Minister.

SCHEDULE.

Therapeutic Substances to which this Act applies.

1.—The substances commonly known as vaccines, sera, toxins, antitoxins and antigens.

2.—The substance commonly known as salvarsan (dioxy-diamino-arseno-benzol-di-hydrochloride) 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.

Saorstát Eireann.

BILLE SUBSTAINTI ICE, 1932.

BILLE

(mar do tugadh isteach)
dá ngairmtear

Acht chun déanamh, iomportáil agus díol substaintí íce (ar a n-áirmhítear substaintí coisctheach agus nochtaithe galar) do rialáil.

An tAire Rialtais Aitiúla agus Slainte Puiblí do thug isteach.

Do horduíodh, ag Dáil Eireann, *do chló-bhuala,* 19*adh Deire Fomhair,* 1932.

BAILE ATHA CLIATH:
FOILLSITHE AG OIFIG AN tSOLATHAIR.

Le ceannach trí aon díoltóir leabhar, no díreach ó Oifig Díolta Foillseacháin Rialtais, 5, Sráid Thobair Phádraig, Baile Atha Cliath, C.2.

Cló-bhuailte ag Cahill & Co., Ltd.

[*Leath-Raol Glan.*]

Wt. 2¹—7. 575. 10/32. C.&Co. (2282).

Saorstát Eireann.

THERAPEUTIC SUBSTANCES BILL, 1932.

BILL

(as introduced)
entitled

An Act to regulate the manufacture, import and sale of therapeutic (including prophylactic and diagnostic) substances.

Introduced by the Minister for Local Government and Public Health.

Ordered, by Dáil Eireann, *to be printed,* 19*th October,* 1932.

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