## HEALTH (No. 2).

3° Elizabeth II., No. XXXIV.

No. 34 of 1954.

## AN ACT to amend the Health Act, 1911-1952.

[Assented to 18th November, 1954.]

BE it enacted by the Queen's Most Excellent Majesty, by and with the advice and consent of the Legislative Council and the Legislative Assembly of Western Australia, in this present Parliament assembled, and by the authority of the same, as follows:-

Short title

- 1. (1) This Act may be cited as the *Health Act* Amendment Act (No. 2), 1954.
- Reprinted Acts Vol. 3, 1950. Approved for reprint, 17th March. 1949.
- (2) In this Act the Health Act, 1911-1952,

Act No. 34 of 1911, as reprinted with amendments to and including Act No. 71 of 1948, incorporated pursuant to the provisions of the Amendments Incorporation Act, 1938, and as further amended by Acts Nos. 25 of 1950, 11 of 1952 and 25 of 1952,

is referred to as the principal Act.

- (3) The principal Act as amended by this Act may be cited as the Health Act, 1911-1954.
- 2. This Act shall come into operation on a date Commence-to be fixed by proclamation.
- 3. Section two of the principal Act is amended \$.2 kmended.
  - (a) adding after the word, "Drugs" in line thirty-seven the words, "Therapeutic Substances";
  - (b) adding after the figure and letter "241E" in line forty-three the following:—

Division 3B.—Manufacture of Therapeutic Substances, ss. 241F-241I.

- 4. Section three of the principal Act is amended s. 3 amended by—
  - (a) adding after the word "dressings" in the last line of the interpretation "Drug" the words "and also includes therapeutic substances;"
  - (b) adding after the interpretation "Street" the following interpretations:—
    - "Therapeutic substance" means a substance which has a therapeutic use and which is prescribed under Division 3B of Part VIII. of this Act to be a therapeutic substance, and includes a surgical ligature, suture or dressing, but does not include a vaccine prepared from microscopic organisms from the body of a person or animal for use in the treatment of that person only.
    - "Therapeutic use" means a use for the purpose of—
      - (a) preventing, diagnosing, curing or alleviating of a disease, ailment, defect or injury in persons;

- (b) influencing, inhibiting or modifying of a physiological process in persons;
- (c) testing of susceptibility to a disease or ailment in persons.

Heading of Part VIII. amended.

5. The heading of Part VIII. of the principal Act which follows section two hundred is amended by adding after the word "DRUGS" the words "THERAPEUTIC SUBSTANCES".

S. 216 amended.

- 6. Section two hundred and sixteen of the principal Act is amended by—
  - (a) adding after the word "Bacteriologist" in lines two and three of subsection (2) the words "or a Physiologist";
  - (b) deleting all words after the word "prescribed" in line three of subsection (8) down to the end of the subsection.

Divison 3B added to Part VIII.

7. The following Division, to follow section two hundred and forty-one E, is added to Part VIII. of the principal Act—

Division 3B.—Manufacture of Therapeutic Substances.

Therapeutic substances to be manufactured on licensed premises.

241F. (1) A person shall not manufacture for sale any therapeutic substance unless the therapeutic substance is manufactured on premises which are licensed by the Commissioner for the purpose.

Application for license.

(2) An application for a license shall be made to the Commissioner by a person who manufactures a therapeutic substance for sale, in the prescribed form accompanied by the prescribed fee.

(3) A person who manufactures for sale a offence. therapeutic substance on any premises, other than premises which are licensed under this division of this Part of this Act, is guilty of an offence.

Penalty: Two hundred pounds and in the case of a continuing offence to a further fine of ten pounds for each day or part of a day during which the offence continues.

241G. A license granted by the Commissioner Duration of licenses and under this division of this Part of this Act—

licenses to stipulate

- (a) shall specify the premises to which it be subject to conditions. relates:
- (b) shall continue in force, unless sooner revoked or suspended under the provisions of this Act, for a period of twelve months from the date of issue and may be renewed from time to time for a like period;
- (c) may be granted subject to such conditions and limitations as the Commissioner considers necessary for the proper production of the therapeutic substances to be manufactured on the premises the subject of the license;
- (d) may specify the therapeutic substances which may alone be manufactured on the premises the subject of the license;
- (e) may be revoked or suspended for such time as the Commissioner thinks fit, if in his opinion the manufacturer of a therapeutic substance has failed to comply with any condition attached to the license of the premises whereon the therapeutic substance is being or is manufactured, or if for any reason the premises, apparatus, processes, materials or staff used or employed in manufacture of a therapeutic substance have become inadequate,

obsolete or unsuitable as the case may be or do not comply with the prescribed standards having regard to the nature of the therapeutic substance being manufactured for sale on the premises.

Appeal against decision of Commissioner.

- 241H. (1) A person aggrieved by a decision of the Commissioner refusing to grant or renew a license or revoking or suspending a license may appeal in manner prescribed against the decision to a Judge of the Supreme Court sitting in open Court or in chambers as the Judge may determine.
- (2) Upon an appeal the Judge may confirm, modify or reverse any decision appealed against or make such other order thereon including an order as to the costs of the appeal as he thinks fit and the decision of the Judge is final.

Regulations.

- 241I. (1) The Governor on the advice of the Advisory Committee established under this Part of this Act, may make regulations prescribing forms, fees and other matters and things which appear to him to be necessary or convenient for the protection of health in relation to therapeutic substances including regulating the manufacture, preparation, package, labelling, storage, carriage, distribution, sale or use of therapeutic substances, prescribing a substance or compound to be a therapeutic substance where used for a prescribed purpose and prescribing the purpose and prescribing a substance to be a therapeutic substance.
- (2) The regulations may prescribe a penalty not exceeding fifty pounds for a breach of any regulation.