EXPLANATORY NOTE

*(This Note is not part of the Regulations, but is intended to indicate their general purport.)*

These Regulations provide for the fees payable in respect of wireless telegraphy licences, other than the sound and television broadcast receiving licences and broadcast relay station licences which are covered by the Wireless Telegraphy (Broadcast Licence Charges) Regulations, 1954 (*S.I. 1954/438*).

Issue and renewal fees for standard form licences are specified in the First Schedule.

Regulation 5 fixes the fees payable when a private mobile radio licence or a demonstration licence is varied by the addition of a wireless telegraphy station.

Regulation 6 provides for the renewal fees payable in respect of licences granted under the Wireless Telegraphy Acts, 1906 to 1926, the fees for standard form licences being specified in the Second Schedule.

The Regulations enable the Postmaster-General to fix the issue fee, renewal fee and (except as regards an experimental licence) the variation fee payable in respect of any special licence which is not on one of the standard forms referred to in the Schedules.

# THERAPEUTIC SUBSTANCES

## 1954 No. 1645

## The Therapeutic Substances Amendment Regulations, 1954

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|---|---|
| *Made* - - - - | 10*th December*, 1954 |
| *Laid before Parliament* | 16*th December*, 1954 |
| *Coming into Operation* | 1*st January*, 1955 |

The Joint Committee constituted by subsection (1) of section 4 of the Therapeutic Substances Act, 1925(**a**), in exercise of the powers conferred on them by sections 1 and 5 of the said Act, after consultation with the Advisory Committee constituted under subsection (2) of the said section 4, hereby make the following regulations :—

**1.**—(1) These regulations may be cited as the Therapeutic Substances Amendment Regulations, 1954, and shall come into operation on the first day of January, 1955.

(2) The principal regulations and these regulations shall be read together as one, and the Therapeutic Substances Regulations, 1952 and 1953, and these regulations may be cited together as the Therapeutic Substances Regulations, 1952 to 1954.

**2.** In these regulations the expression " the principal regulations " means the Therapeutic Substances Regulations, 1952(**b**), as amended by the Therapeutic Substances Amendment Regulations, 1953(**c**).

(a) 15 & 16 Geo. 5. c. 60. (b) S.I. 1952/1937 (1952 III, p. 3420).
(c) S.I. 1953/1172 (1953 II, p. 2289).

**3.** Oxytetracycline which is intended for parenteral injection, and preparations of oxytetracycline which are intended for such injection, are hereby added to the Schedule to the Therapeutic Substances Act, 1925, as being substances the purity or potency of which cannot be adequately tested by chemical means.

**4.**—(1) In proviso (ii) to paragraph (1) of regulation 7 of the principal regulations (which provides that in the case of smallpox vaccine the particulars required by that paragraph may, instead of being printed, written or marked as therein prescribed, be printed or written in indelible ink on a label or wrapper affixed to any package in which the container is offered for sale) for the words "a label or wrapper affixed to any package in which the container is offered for sale" there shall be substituted the words "the package in which the container is offered for sale or on a label affixed to the package".

(2) In paragraph (2) of the said regulation 7 (which requires certain particulars to be contained on the label on the container of a therapeutic substance or on a label or wrapper attached to the package in which the container is issued for sale) for the words from the beginning to "issued for sale" the following words shall be substituted:—

> "(2) The following particulars and such further particulars, if any, as may be specified in the relative schedule shall be printed or written in indelible ink on the label borne by the container of a therapeutic substance or indelibly marked in the body of the container, or shall be printed or written in indelible ink on the package in which the container is offered for sale or on a label affixed to the package";

and any reference, however expressed, in any other provision of the principal regulations to a label or wrapper on a package in which a container is enclosed shall be construed accordingly.

**5.** In regulation 22 of the principal regulations (which added to the schedule to the Act dimercaprol and its derivatives, and preparations thereof) for the words "Dimercaprol and its derivatives, and preparations thereof" there shall be substituted the words "Dimercaprol which is intended for parenteral injection, and preparations of dimercaprol which are intended for such injection".

**6.** The provisions contained in the first schedule to these regulations shall be substituted for the provisions contained in the sixth schedule to the principal regulations.

**7.** The provisions contained in the second schedule to these regulations (which relate to oxytetracycline and preparations thereof) shall be inserted at the end of the ninth schedule to the principal regulations (which relates to antibiotics) as part V thereof.

**8.**—(1) In sub-paragraph (*c*) of paragraph 2 of part I of the tenth schedule to the principal regulations (which relates to the method of estimating the haemoglobin content of a donor's blood) for the words "as estimated against the National Physical Laboratory Haldane haemoglobinometer colour standard (B.S.S. No. 1079-1942)" there shall be substituted the words "as estimated against the National Physical Laboratory Haldane Haemoglobinometer Colour Standard (British Standard 1079: 1952).

(2) In paragraph 5 of part II of the said schedule (which provides that a container of whole human blood shall be maintained within certain limits of

temperature except during such period, not exceeding thirty minutes, as may be necessary for examination or transfer) for the words "thirty minutes" there shall be substituted the words "one hour".

**9.**—(1) In sub-paragraph (1) of paragraph 9 of part IV of the third schedule to the principal regulations (which specifies provisions of that part which are not to apply to dried smallpox vaccine) the words "and sub-paragraph (2) of paragraph 8" shall be omitted.

(2) The following sub-paragraph shall be inserted after sub-paragraph (4) of the said paragraph 9:—

"(4A) Sub-paragraph (2) of paragraph 8 of this part of this schedule, in its application to dried smallpox vaccine, shall have effect as if for the words "the date on which it is removed from cold storage for issue" there were substituted the words "the date on which the material has last been tested for potency".

## FIRST SCHEDULE

## INSULIN AND PREPARATIONS OF INSULIN

### PART I

### GENERAL PROVISIONS APPLICABLE TO INSULIN

*Definition and proper name*

1. Insulin is a preparation of the specific antidiabetic principle of the pancreas. Its proper name is "insulin".

*Standard Preparation*

2. The standard preparation of insulin is a quantity of insulin kept at the National Institute for Medical Research, London.

*Unit of standardization*

3. The unit of insulin for the purposes of these regulations is the specific activity contained in such an amount of the standard preparation of insulin as the Medical Research Council may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

*Quality*

4. Insulin which is issued as a watery solution shall have a pH value lying between 2·5 and 3·5.

*Test for potency*

5. Subject to the provisions of this schedule, insulin shall be tested biologically by comparison with the standard preparation, and the potency and the fiducial limits of error ($P = 0{\cdot}95$) of the potency shall be calculated from the results of the test. The estimated potency of a preparation shall be not greater than 111 per cent. and not less than 90 per cent. of the stated potency. The fiducial limits of error ($P = 0{\cdot}95$) of the estimated potency shall lie between 80 and 125 per cent. of the stated potency.

*Method of issue*

6. Insulin shall not be issued in a mixture with any other therapeutic agent without the consent of the licensing authority.

### PART II

### GENERAL PROVISIONS APPLICABLE TO ALL PREPARATIONS OF INSULIN

*Definitions and proper names*

1. The proper name of a preparation of insulin or of a mixture of insulin with another therapeutic substance for which a proper name is not expressly provided in this schedule is "insulin" together with such words or abbreviations as may be approved by the licensing authority as descriptive of that preparation or mixture.

*Test for potency*

2.—(1) Preparations of insulin shall be tested biologically by comparison with the standard preparation of insulin in the manner provided by paragraph 5 of part I of this schedule:

Provided that—

(*a*) globin zinc insulin shall be so tested by comparison with the standard preparation of globin zinc insulin;

(*b*) the licensing authority may exempt from this requirement any preparation of insulin other than globin zinc insulin.

(2) A preparation of insulin which is tested in accordance with the foregoing sub-paragraph need not be made of insulin which has been tested in accordance with the said paragraph 5.

*Method of issue*

3. Preparations of insulin shall not be issued in a mixture with any other therapeutic agent without the consent of the licensing authority.

*Labelling*

4. The container of a liquid preparation of insulin shall indicate the strength as the number of units of insulin per millilitre, and the label on the container of a solid preparation in tablet form shall indicate the strength as the number of units of insulin in each tablet:

Provided that if the preparation is a preparation of globin zinc insulin the units indicated shall be units of globin zinc insulin.

## Part III

## Long-acting Insulins and Preparations of Long-acting Insulins

### A

### General Provisions

*Definition*

1. Long-acting insulins consist of insulin prepared in such a way or combined with such a substance or substances that its hypoglycaemic action after parenteral injection is prolonged.

*Test for prolongation of action*

2. Long-acting insulins shall be tested by comparison with the standard preparation of insulin, by a method approved by the licensing authority, for their power of prolonging insulin hypoglycaemia:

Provided that the licensing authority may exempt any preparation from this requirement.

### B

### Special Provisions Applicable to Globin Zinc Insulin

*Definition and proper name*

1. Globin zinc insulin is a preparation of the zinc salt of insulin combined with globin. Its proper name is " globin zinc insulin ".

*Standard preparation*

2. The standard preparation of globin zinc insulin is a quantity of globin zinc insulin kept at the National Institute for Medical Research, London.

*Unit of standardization*

3. The unit of globin zinc insulin for the purposes of these regulations is the specific activity contained in such an amount of the standard preparation of globin zinc insulin as the Medical Research Council may from time to time indicate.

C

SPECIAL PROVISIONS APPLICABLE TO PROTAMINE ZINC INSULIN

*Definition and proper name*

1. Protamine zinc insulin is the complex produced by the interaction of insulin with a suitable protamine and zinc chloride. Its proper name is " protamine zinc insulin ".

*Quality*

2.—(1) The quantity of protamine in the preparation shall not be less than 1·0 milligrams nor more than 1·5 milligrams of protamine sulphate for each 100 units of insulin.

(2) The liquor from which the precipitate of protamine zinc insulin has been removed shall not contain more than 4 per cent. of the stated activity of the original protamine zinc insulin.

D

SPECIAL PROVISIONS APPLICABLE TO ISOPHANE INSULIN

*Definition and proper name*

1. Isophane insulin consists substantially of a crystalline complex of insulin, protamine and zinc, suspended in a buffered medium. Its proper name is " isophane insulin ".

*Quality*

2.—(1) The quantity of protamine in the preparation shall not be less than 0·3 milligrams nor more than 0·6 milligrams of protamine sulphate for each 100 units of insulin.

(2) The suspension shall have a pH value lying between 7·1 and 7·4.

*Test for freedom from protaminase*

3. Isophane insulin shall be subjected to the following stability test to ensure its freedom from contamination with protaminase:—

A sample of 40 millilitres of isophane insulin shall be divided into two equal portions. One portion shall be centrifuged and the deposit washed with alcohol, dried and weighed. The other portion shall be placed in an incubator at 37°C and left for 30 days. It shall then be removed from the incubator and centrifuged, and the deposit similarly washed with alcohol, dried and weighed. The loss in weight after 30 days incubation at 37°C shall not exceed 10 per cent. of the initial weight.

E

SPECIAL PROVISIONS APPLICABLE TO INSULIN ZINC SUSPENSIONS

*Definition and proper name*

1. Insulin zinc suspensions are preparations of insulin with zinc in a suitable buffer, such that the insulin is in a form insoluble in water. The proper name of any such preparation is " insulin zinc suspension " followed in parentheses by the word " crystalline " if the insulin is almost wholly in crystalline form or by the word " amorphous " if the insulin is almost wholly in amorphous form.

2. The liquor from which the precipitate of insulin zinc suspension has been removed shall not contain more than 4 per cent. of the stated activity of the original insulin zinc suspension.

## SECOND SCHEDULE

### " PART V

### OXYTETRACYCLINE

*Definition*

1. Oxytetracycline is an antimicrobial organic base produced by *Streptomyces rimosus* and has the chemical structure 4-dimethylamino-1:4:4a:5:5a:6:11:12a-octahydro-3:5:6:10:12:12a-hexahydroxy-6-methyl-1:11 - dioxonaphthacene-2-carboxyamide. The expression includes any salt or derivative of the said base

which does not contain organically bound chlorine, and any substance the chemical and biological properties of which are identical with or similar to those of any of the said substances but which is not produced by living organisms.

*Proper name*

2. The proper name of oxytetracycline or a preparation of oxytetracycline is "oxytetracycline" qualified by a word or words approved by the licensing authority as indicating the nature of the preparation.

*Standard preparation*

3. The standard preparation is a quantity of a dihydrate of oxytetracycline.

*Strength*

4.—(1) Salts of oxytetracycline with inorganic acids, if in solid form, shall not be issued with a potency of less than 830 units per milligram.

(2) In the case of other salts or derivatives of oxytetracycline or preparations thereof the minimum permitted potency shall be determined by the licensing authority.

*Quality*

5. A salt of oxytetracycline shall form an initially clear solution when the dried substance is dissolved in distilled water in a concentration of 10,000 units per millilitre. The pH value of such a solution in the case of a salt of oxytetracycline with an inorganic acid shall lie between 2·3 and 3·0.

*Test for freedom from abnormal toxicity*

6. The number of units of oxytetracycline for the purpose of the test for freedom from abnormal toxicity shall be not less than 1,000.

*Test for freedom from pyrogenic substances*

7. The number of units of oxytetracycline for the purpose of the test for freedom from pyrogenic substances shall be not less than 5,000 units per kilogram of the rabbit's weight.

*Test for freedom from histamine-like substances*

8. Paragraph 8 of part III of this schedule shall apply to oxytetracycline as if for references to streptomycin there were substituted references to oxytetracycline.

*Modification of part I in relation to oxytetracycline*

9. In their application to oxytetracycline, references in paragraphs 5 and 6 of part I of this schedule to any solvent shall be construed as references to any solvent specifically recommended by the licensee for the reconstitution of oxytetracycline, or if no solvent is so recommended to a buffer solution containing 3·75 grammes of glycine and 2·1 grammes of sodium hydroxide in one litre."

These regulations were made by the aforesaid Joint Committee this tenth day of December, nineteen hundred and fifty-four.

*Iain Macleod,*
*James Stuart,*
*Dehra Parker,*
Members of the Joint Committee.

*W. G. Honnor,*
Clerk to the Joint Committee.

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## EXPLANATORY NOTE

*(This Note is not part of the regulations, but is intended to indicate their general purport.)*

These regulations—

(*a*) add to the schedule to the Therapeutic Substances Act, 1925, oxytetracycline which is intended for parenteral injection and preparations thereof which are intended for such injection (regulations 3 and 7 and second schedule);

(*b*) make a number of detailed amendments in the Therapeutic Substances Regulations, 1952 (regulations 4, 5, 8 and 9); and

(*c*) substitute for the provisions of the Regulations of 1952 relating to insulin more up-to-date provisions (regulation 6 and first schedule).

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# 1954 No. 1646

# The Therapeutic Substances (Control of Sale and Supply) Regulations, 1954

| | |
|---|---|
| *Made* - - - - | 10*th December*, 1954 |
| *Laid before Parliament* | 16*th December*, 1954 |
| *Coming into Operation* | 1*st January*, 1955 |

Whereas the substances hereinafter mentioned appear to the Minister of Health, the Secretary of State and the Minister of Health and Local Government for Northern Ireland (hereinafter called "the Ministers") to be substances which are capable of causing danger to the health of the community if used without proper safeguards;

Now, therefore, the Ministers, in exercise of the powers conferred on them by subsection (1) of section 2 of the Penicillin Act, 1947(**a**), as enacted in subsection (1) of section 1 of the Therapeutic Substances (Prevention of Misuse) Act, 1953(**b**), and of all other powers enabling them in that behalf, jointly, after consultation with the Medical Research Council, hereby make the following regulations:—

**1.**—(1) These regulations may be cited as the Therapeutic Substances (Control of Sale and Supply) Regulations, 1954, and shall come into operation on the first day of January, 1955.

(2) The Interpretation Act, 1889(**c**), applies to the interpretation of these regulations as it applies to the interpretation of an Act of Parliament.

**2.** The Penicillin Act, 1947, as amended by subsequent enactments(**d**), shall apply—

(*a*) to the substances the names of which are shown in the first column of the schedule to these regulations and the descriptions of which are shown in the second column thereof;

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(**a**) 10 & 11 Geo. 6. c. 29.
(**b**) 1 & 2 Eliz. 2. c. 32.
(**c**) 52 & 53 Vict. c. 63.
(**d**) 14 & 15 Geo. 6. c. 13; 1 & 2 Eliz. 2. c. 32.