THERAPEUTIC SUBSTANCES

The Therapeutic Substances Amendment Regulations, 1949

1949 No. 1846

Made - - - -	*29th September*, 1949
Laid before Parliament	*30th September*, 1949
Coming into Operation	*1st October*, 1949

M.H. 109564.

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

PART I

Preliminary

1.—(1) These regulations may be cited as the Therapeutic Substances Amendment Regulations, 1949, and the Therapeutic Substances Regulations, 1931 to 1948, and these regulations shall be read as one and may be cited together as the Therapeutic Substances Regulations, 1931 to 1949.

(2) These regulations shall come into operation on the first day of October, 1949.

2.—(1) In these regulations " the principal regulations " means the Therapeutic Substances Regulations, 1931(b), as amended by the Therapeutic Substances Amendment Regulations, 1935(c), the Therapeutic Substances (Amendment) Regulations, 1937(d), the Therapeutic Substances Amendment Regulations, 1939(e), the Therapeutic Substances Amendment Regulations, 1944(f), the Therapeutic Substances Amendment Regulations, 1946(g), and the Therapeutic Substances Amendment Regulations, 1948(h).

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

PART II

Addition of substance to Schedule to Act

3. Streptomycin as defined in the schedule added by these regulations to the principal regulations shall be added to the schedule to the Act as being a substance the purity and potency of which cannot be adequately tested by chemical means.

(a) 15 & 16 Geo. 5. c. 60.
(b) S.R. & O. 1931 (No. 633) p. 1311.
(c) S.R. & O. 1935 (No. 580) p. 1668.
(d) S.R. & O. 1937 (No. 767) p. 2294.
(e) S.R. & O. 1939 (No. 1395) II, p. 3172.
(f) S.R. & O. 1944 (No. 370) I, p. 1009.
(g) S.R. & O. 1946 (No. 467) I, p. 1590.
(h) S.I. 1948 (No. 2418) I, p. 4067.
(i) 52 & 53 Vict. c. 63.

PART III

Amendments of the principal regulations

4.—(1) In regulation 15 of the principal regulations (which requires sterility tests to be made in the case of the substances therein mentioned) after paragraph (*h*) there shall be inserted the following paragraph:—

"(i) streptomycin".

(2) The following schedule shall be inserted in the principal regulations after the Ninth Schedule thereto:—

TENTH SCHEDULE

STREPTOMYCIN

Definition

1. "Streptomycin" means any antimicrobial complex organic base or mixture of such bases produced by *Streptomyces griseus* or other living organism which—

(*a*) yields on hydrolysis by mineral acids the base streptidine (meso-2:4:5:6-tetrahydroxy-1:3-diguanidocyclohexane); and

(*b*) yields on hydrolysis by a 4% solution of sodium hydroxide the substance maltol (3-hydroxy-2-methyl-γ-pyrone);

and includes any salt or derivative, or salt of a derivative, of any such base, any mixture of any of the substances aforesaid, and any substance the chemical and biological properties of which are identical with or similar to those of any of the substances aforesaid but which is not produced by living organisms.

Proper name

2. The proper name of streptomycin is "streptomycin" qualified by a word or words indicating the nature of the preparation, as, for example, "streptomycin sulphate".

Standard Preparation

3. The standard preparation is a preparation of streptomycin kept at the National Institute for Medical Research, London.

Unit of standardisation

4. The unit of streptomycin for the purpose of these regulations is the activity contained in such an amount of the standard preparation as may be indicated from time to time by the Medical Research Council.

Quality

5. Streptomycin shall form a clear solution with a pH value lying between 5.0 and 7.0 when the dried substance is reconstituted with distilled water in a concentration of 5,000 units per c.c.

Strength

6.—(1) Streptomycin shall be tested for potency by comparative tests in relation to the standard preparation, by a method approved by the licensing authority. The potency so determined shall be expressed in units per milligram in the case of streptomycin in solid form, and in units per c.c. in the case of solutions.

(2) Streptomycin with a potency, in the case of streptomycin in solid form, of less than 300 units per milligram or, in the case of a solution, of less than 2,000 units per c.c., shall not be issued:

Provided that the licensing authority may authorise, with or without conditions, the issue for specified purposes of streptomycin which does not satisfy the said standards of potency.

Test for freedom from abnormal toxicity

7. Streptomycin shall be subjected to the following test for absence of abnormal toxicity:—

A quantity of the streptomycin containing not less than 1,000 units, dissolved, in the case of streptomycin in solid form, in a volume not exceeding 0.5 c.c. of a watery solution shall be injected intravenously into each of five normal mice each weighing between 17 and 22 grammes. The sample shall be treated as having passed the test if either—

(*a*) the injection does not cause death in any of the mice within twenty-four hours, or

(*b*) the injection having caused death in one only of the mice within that period, similar injection of five other such mice does not cause the death of any of those mice within twenty-four hours.

Test for freedom from pyrogenic substances

8. Streptomycin shall be subjected to the following test for freedom from pyrogenic substances:—

There shall be injected intravenously into each of three normal healthy rabbits each weighing not less than 1.5 kilograms a quantity of the streptomycin containing, in the case of each rabbit, not less than 2,000 units per kilogram of the rabbit's weight, dissolved, in the case of streptomycin in solid form, in not more than 5 c.c. of water or physiological saline. The body temperature of the rabbits shall be recorded at least once during the hour before and three times in the three hours after the injection, one such record being made between seventy-five and ninety minutes after the injection. The sample shall be treated as having passed the test if the average maximum increase of temperature shown by the three rabbits does not exceed 0.6° C.

Test for freedom from histamine-like substances

9. Streptomycin shall be subjected to the following test for freedom from histamine-like substances:—

A solution of the streptomycin, containing not less than 3,000 units per c.c., shall be injected intravenously, in a precisely determined volume within the range corresponding to 0.1 to 0.25 c.c. per kilogram of the cat's weight, into a cat anaesthetized with chloralose or a suitable barbiturate.

The sample shall be treated as having passed the test, if the injection produces a smaller fall of arterial blood pressure than the injection into the same cat of an equal volume of a solution of a histamine salt containing 1 microgram of histamine base per c.c.

Labelling

10. If streptomycin as issued for sale is mixed with any substance the label on the container shall state the nature of that substance and the minimum number of units of streptomycin per gramme of the mixture, in the case of a solid preparation, or per c.c. thereof in the case of a solution or suspension.

These regulations were made by the aforesaid Joint Committee this 29th day of September, nineteen hundred and forty-nine.

Aneurin Bevan,
Arthur Woodburn,
Dehra Parker,
Members of the Joint Committee.

F. F. Marchbank,
Clerk to the Joint Committee.

EXPLANATORY NOTE

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

These regulations amend the Therapeutic Substances Regulations, 1931, by adding streptomycin to the schedule to the Therapeutic Substances Act, 1925, (thus rendering it subject to control under that Act), and inserting in those regulations a schedule dealing with the preparation, testing and labelling of streptomycin.

TOWN AND COUNTRY PLANNING, ENGLAND

[*See* also Class 5 of the Classified List of Local Instruments printed at the end of this volume.]

1. *Claims for Depreciation of Land Values.*
2. *Control of Advertisements*, p. 4025.
3. *Development of Land*, p. 4028.
4. *Erection of Industrial Buildings*, p. 4032.
5. *Isles of Scilly*, *p.* 4033.
6. *Minerals*, p. 4035.
7. *Planning Payments (War Damage)*, p. 4037.

1. CLAIMS FOR DEPRECIATION OF LAND VALUES

The Claims for Depreciation of Land Values (Mineral Undertakings) Regulations, 1949

1949 No. 1176

Made - - - -	23*rd June*, 1949
Laid before Parliament	25*th June*, 1949
Coming into Operation	30*th June*, 1949

B3573

The Minister of Town and Country Planning, in exercise of the powers conferred on him by Sections 60 and 111 of the Town and Country Planing Act, 1947(**a**), and of all other powers enabling him in that behalf, hereby makes the following Regulations:—

1. These Regulations may be cited as the Claims for Depreciation of Land Values (Mineral Undertakings) Regulations, 1949, and shall come into operation on the thirtieth day of June, 1949.

2.—(1) In these Regulations the following expressions have the meanings hereby assigned to them:—

(i) "the Act" means the Town and Country Planning Act, 1947;

(ii) "claim" has the meaning assigned to it by the Claims for Depreciation of Land Values Regulations, 1948(**b**);

(iii) "mineral undertaker" means any person engaged in the winning and working of minerals in, on, or under land, whether by surface or underground working, other than any such minerals as are mentioned in paragraph 5 of the Third Schedule to the Act and other than minerals vested in the National Coal Board.

(a) 10 & 11 Geo. 6. c. 51. (b) S.I. 1948 (No. 902) I, p. 4105.