THERAPEUTIC SUBSTANCES

1953 No. 1172

The Therapeutic Substances Amendment Regulations, 1953

Made - - - -	31*st July*, 1953
Laid before Parliament	31*st July*, 1953
Coming into Operation	1*st September*, 1953

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, 1953, and shall come into operation on the first day of September, 1953.

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

2. In these regulations the expression "the principal regulations" means the Therapeutic Substances Regulations, 1952(b).

3. Aureomycin which is intended for parenteral injection, and preparations containing aureomycin 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. The special provisions applicable to aureomycin set out in the schedule to these regulations shall be inserted at the end of the ninth schedule to the principal regulations (which relates to antibiotics) as part IV.

5. At the end of paragraphs (6) and (7) of regulation 14 of the principal regulations (which so far as is material provide that where after testing a sample of a batch of a therapeutic substance for sterility any micro-organism is found the batch shall be treated as not sterile and the material contained in the batch shall not be issued or used as part of a further batch) there shall be inserted the words "unless or until the material has been resterilised and has passed the foregoing tests".

SCHEDULE

"PART IV

SPECIAL PROVISIONS APPLICABLE TO AUREOMYCIN

Definition

1. Aureomycin is any antimicrobial weakly basic substance or mixture of such basic substances produced by *Streptomyces aureofaciens* which has the following characteristics:—

(*a*) the substance is a yellow crystalline compound containing nitrogen and non-ionic chlorine;

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

(*b*) a 0.1 per cent. watery solution of the substance after heating at 100° C. for one minute in the presence of buffer having a pH value of 7.6 exhibits a strong blue fluorescence in ultra-violet light, and on heating with hydrochloric acid turns orange-yellow ;

and any substance the chemical and biological properties of which are identical with or similar to those of any such substance but which is not produced by living organisms.

Proper name

2. The proper name of aureomycin or a preparation of aureomycin is "aureomycin" 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 dry aureomycin hydrochloride.

Strength

4.—(1) Salts of aureomycin with inorganic acids, if in solid form, shall not be issued with a potency of less than 900 units per milligram.

(2) In the case of other salts or derivatives of aureomycin the minimum permitted potency shall be such as shall be determined by the licensing authority.

Quality

5. A salt of aureomycin shall form a clear solution when the dried substance is dissolved in distilled water in a concentration of 5,000 units per millilitre. The pH value in the case of a saturated watery solution of a salt of aureomycin with an inorganic acid shall lie between 2.3 and 3.3.

Test for freedom from abnormal toxicity

6. The number of units of aureomycin 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 aureomycin 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 aureomycin as if for references to streptomycin there were substituted references to aureomycin."

These regulations were made by the aforesaid Joint Committee this thirty-first day of July, nineteen hundred and fifty-three.

Iain Macleod,

James Stuart,

Dehra Parker,

Members of the Joint Committee.

W. G. Honnor,

Clerk to the Joint Committee.