STATUTORY INSTRUMENTS

1967 No. 1195

THERAPEUTIC SUBSTANCES

The Therapeutic Substances (Manufacture of Antibiotics) Amendment Regulations 1967

Made - - -	*4th August* 1967
Laid before Parliament	11*th August* 1967
Coming into Operation	1*st September* 1967

The Joint Committee constituted by section 4(1) of the Therapeutic Substances Act 1956(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 section 4(2) of the said Act, hereby make the following regulations:—

Citation, Commencement and Interpretation

1.—(1) These regulations may be cited as the Therapeutic Substances (Manufacture of Antibiotics) Amendment Regulations 1967 and shall come into operation on 1st September 1967.

(2) The Therapeutic Substances (Manufacture of Antibiotics) Regulations 1966(b) and these regulations may be cited together as the Therapeutic Substances (Manufacture of Antibiotics) Regulations 1966 and 1967.

(3) The Interpretation Act 1889(c) shall apply to the interpretation of these regulations as it applies to the interpretation of an Act of Parliament.

Inclusion of substances in schedule 1 *to the Therapeutic Substances Act* 1956

2.—(1) Gentamicin and Capreomycin, preparations thereof, and mixtures which include any of the foregoing, in each case if intended for parenteral injection, are hereby added to schedule 1 to the Therapeutic Substances Act 1956 as being substances the purity or potency of which cannot be adequately tested by chemical means.

(2) The expression "parenteral injection" in paragraph (1) of this regulation has the same meaning as in the Therapeutic Substances (Manufacture of Antibiotics) Regulations 1966.

Amendment of the Therapeutic Substances (Manufacture of Antibiotics) Regulations 1966

3. The Therapeutic Substances (Manufacture of Antibiotics) Regulations 1966 shall be amended as follows:—

(*a*) in regulations 69 and 74(1) (which refer to the definition of neomycin and of the lincomycins respectively) for the word "antimicrobal" there shall be substituted the word "antimicrobial";

(*b*) after regulation 77 there shall be added the following regulations—

(a) 4 & 5 Eliz. 2. c. 25. (b) S.I. 1966/505 (1966 I, p.1049). (c) 52 & 53 Vict. c. 63.

"PART XV

SPECIAL PROVISIONS RELATING TO GENTAMICIN

Definition

78. Gentamicin is any antimicrobial basic substance or mixture of such substances produced by the strain of *Micromonospora purpurea* which on 1st September 1967 is numbered NRRL 2953 in the culture collection of the Northern Utilisation Research and Development Branch of the United States Department of Agriculture. The expression includes any salt or derivative, or salt of a derivative of gentamicin and any substance the chemical and biological properties of which are identical with or similar to any of the said substances but which is produced by other means.

Standard preparation

79. The standard preparation of gentamicin is one of gentamicin sulphate.

Strength

80.—(1) Gentamicin sulphate shall not be issued in solid form with a potency of less than 590 units per milligram.

(2) The minimum permitted potency of any other salt or derivative of gentamicin shall be such as shall be specified by the licensing authority in relation to the particular salt or derivative.

Quality

81.—(1) Where gentamicin is a mixture in terms of regulation 78 of these regulations, the proportions of the substances comprised in the mixture and the method used to determine such proportions shall be such as shall be approved by the licensing authority.

(2) Gentamicin sulphate shall form a clear solution with a pH value lying between 3.5 and 5.5 when the dried substance is dissolved in purified water at a concentration of 40,000 units per millilitre.

Number of units for purposes of tests

82.—(1) The number of units of gentamicin sulphate for the purpose of the test for freedom from abnormal toxicity shall be not less than 500.

(2) The number of units of gentamicin sulphate for the purpose of the test for freedom from pyrogenic substances shall be not less than 10,000 units per kilogram of the weight of each rabbit used in the test.

(3) The number of units of any other salt or derivative of gentamicin for the purpose of the tests for freedom from abnormal toxicity or freedom from pyrogenic substances shall be such as shall be specified by the licensing authority in relation to the particular salt or derivative.

PART XVI

SPECIAL PROVISIONS RELATING TO CAPREOMYCIN

Definition

83. Capreomycin is any antimicrobial polypeptide or mixture of such polypeptides produced by the strain of *Streptomyces capreolus* which on 1st September 1967 is numbered NRRL 2773 in the culture collection of the Northern

Utilisation Research and Development Branch of the United States Department of Agriculture, and it yields on hydrolysis with mineral acids the amino-acids α : β-diamino-propionic acid and α-(2-imino-hexahydro-4-pyrimidyl) glycine together with serine, alanine and β-lysine. The expression includes any salt or derivative, or salt of a derivative of any such polypeptide and any substance the chemical and biological properties of which are identical with or similar to any of the substances aforesaid but which is produced by other means.

Standard preparation

84. The standard preparation of capreomycin is one of capreomycin disulphate.

Strength

85.—(1) Capreomycin disulphate shall not be issued in solid form with a potency of less than 700 units per milligram.

(2) The minimum permitted potency of any other salt or derivative of capreomycin shall be such as shall be specified by the licensing authority in relation to the particular salt or derivative.

Quality

86.—(1) Where capreomycin is a mixture in terms of regulation 83 of these regulations the proportions of the substances comprised in the mixture and the method used to determine such proportions shall be such as shall be approved by the licensing authority.

(2) Capreomycin disulphate shall form a clear solution with a pH value lying between 4.5 and 7.5 when the dried substance is dissolved in purified water at a concentration of 18,000 units per millilitre.

Number of units for purposes of tests

87.—(1) The number of units of capreomycin disulphate for the purpose of the test for freedom from abnormal toxicity shall be not less than 700.

(2) The number of units of capreomycin disulphate for the purpose of the test for freedom from pyrogenic substances shall be not less than 7,000 units per kilogram of the weight of each rabbit used in the test.

(3) The number of units of any other salt or derivative of capreomycin for the purpose of the tests for freedom from abnormal toxicity or freedom from pyrogenic substances shall be such as shall be specified by the licensing authority in relation to the particular salt or derivative.

Freedom from histamine-like substances

88.—(1) Capreomycin shall be free from histamine-like substances. The number of units of capreomycin disulphate for the purpose of the test shall be not less than 3,000 units per millilitre of the solution.

(2) The number of units of any other salt or derivative of capreomycin for the purpose of the test shall be such as shall be specified by the licensing authority in relation to the particular salt or derivative.".

These regulations were made by the aforesaid Joint Committee on 4th August 1967.

Kenneth Robinson,
William Ross,
Wm. J. Morgan,
Members of the Joint Committee.

W. F. Farrant,
Clerk to the Joint Committee.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These regulations, made under Part I of the Therapeutic Substances Act 1956, extend the provisions of the Therapeutic Substances (Manufacture of Antibiotics) Regulations 1966 by adding gentamicin and capreomycin and derivatives of each of those substances, in each case if intended for parenteral injection, to the substances listed in Schedule 1 to the Act and by including provisions for their definition and method of preparation, and for testing them for freedom from toxicity and from pyrogenic substances.