STATUTORY INSTRUMENTS

1968 No. 906

THERAPEUTIC SUBSTANCES

The Therapeutic Substances (Manufacture of Antibiotics) Amendment Regulations 1968

Made - - -	10*th June* 1968
Laid before Parliament	17*th June* 1968
Coming into Operation	1*st July* 1968

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 1968 and shall come into operation on 1st July 1968.

(2) The Therapeutic Substances (Manufacture of Antibiotics) Regulations 1966 and 1967(**b**) and these regulations may be cited together as the Therapeutic Substances (Manufacture of Antibiotics) Regulations 1966 to 1968.

(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) The rifamycins, 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 and 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 *and* 1967

3. The Therapeutic Substances (Manufacture of Antibiotics) Regulations 1966, as amended, shall be further amended by adding after regulation 88 the following regulations—

(**a**) 1956 c. 25. (**b**) S.I. 1966/505, 1967/1195 (1966 I, p. 1049; 1967 II, p. 3498).
(**c**) 1889 c. 63.

PART XVII

SPECIAL PROVISIONS RELATING TO THE RIFAMYCINS

Definitions and proper name

89.—(1) The substances collectively referred to in these regulations as the rifamycins are a group of related antimicrobial macrolactams produced by the growth of *Streptomyces mediterranei* and containing the chemical structure of 11-acetoxy-7,9,15-trihydroxy-13-methoxy-2,6,8,10,12-pentamethylpentadeca-2,4, 14-trienoic acid amide, attached by the nitrogen atom and by the oxygen atom in the 15-position respectively to the 7- and 2- positions of a 5,6,9-trioxygenated 2,4-dimethyl-1-oxonaphtho [2,1-b] furan. The expression includes the substance described in paragraph (2) of this regulation, any salt or ester or salt of an ester of any of the rifamycins, and any substance the chemical or biological properties of which are identical with or similar to those of the said substances but which is produced by other means.

(2) Rifamide is an antimicrobial base produced from a rifamycin known as rifamycin B and has the chemical structure of 11-acetoxy-7,9,15-trihydroxy-13-methoxy-2,6,8,10,12-pentamethylpentadeca-2,4,14-trienoic acid amide, attached by the nitrogen atom and by the oxygen atom in the 15-position respectively to the 7- and 2- positions of 5,6-dihydroxy-2,4-dimethyl-1-oxonaphtho [2,1-b] furan-9-oxyacetic acid diethylamide. Its proper name is "rifamide".

Standard preparation

90.—(1) The standard preparation of rifamide is one of the sodium salt of rifamide.

(2) The standard preparation of any other of the rifamycins is one of such substance as may be indicated with respect thereto by the licensing authority.

Strength

91.—(1) Rifamide shall not be issued in solid form with a potency of less than 900 units per milligram.

(2) The minimum permitted potency of any other of the rifamycins or of a preparation of any of the rifamycins shall be such as shall be determined by the licensing authority.

Number of units for purposes of tests

92.—(1) The number of units of rifamide for the purpose of the test for freedom from abnormal toxicity shall be not less than 4,000.

(2) The number of units of rifamide 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 of the rifamycins or of a preparation of any of the rifamycins for the purpose of the test for freedom from abnormal toxicity or freedom from pyrogenic substances shall be such as may be specified by the licensing authority in relation to the particular rifamycin or preparation.

Freedom from histamine-like substances

93. The rifamycins shall be free from histamine-like substances. The number of units for the purpose of the test shall be, in the case of rifamide, not less than 3,000 units per millilitre of the solution, and in the case of any other of the rifamycins or of a preparation of any of the rifamycins, such number as may be specified by the licensing authority in relation to the particular rifamycin or preparation.".

These regulations were made by the aforesaid Joint Committee on 10th June 1968.

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 and 1967 by adding the rifamycins, and derivatives of those substances, in each case if intended for parenteral injection, to the substances listed in schedule 1 to the Act, and include provisions for their definition, standards of strength and for tests for freedom from pyrogenic substances, abnormal toxicity and histamine-like substances.