STATUTORY INSTRUMENTS

1971 No. 888

THERAPEUTIC SUBSTANCES

The Therapeutic Substances (Manufacture of Antibiotics) Amendment Regulations 1971

Made - - -	*27th May* 1971
Laid before Parliament	*8th June* 1971
Coming into Operation	*1st July* 1971

The Joint Committee constituted by section 4(1) of the Therapeutic Substances Act 1956(**a**), as amended by article 2(2) of and Schedule 1 to the Transfer of Functions (Wales) Order 1969(**b**), 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 1971 and shall come into operation on 1st July 1971.

(2) The Therapeutic Substances (Manufacture of Antibiotics) Regulations 1966 to 1969(**c**) and these regulations may be cited together as the Therapeutic Substances (Manufacture of Antibiotics) Regulations 1966 to 1971.

(3) Any reference in these regulations to any provision of the general regulations shall be construed as a reference to that provision as amended, extended or re-enacted by any subsequent regulations made under Part I of the Act.

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

(5) In these regulations, unless the context otherwise requires—

"the Act" means the Therapeutic Substances Act 1956 ;

"the general regulations" means the Therapeutic Substances (Manufacture and Importation) General Regulations 1963, as amended (**e**) ;

(**a**) 1956 c. 25. (**b**) S.I. 1969/388 (1969 I, p. 1070).
(**c**) S.I. 1966/505, 1967/1195, 1968/906, 1969/1707 (1966 I, p. 1049; 1967 II, p. 3498; 1968 II, p. 2389; 1969 III, p. 5378). (**d**) 1889 c. 63.
(**e**) S.I. 1963/1450, 1964/1076, 1966/498, 1971/666 (1963 II, p. 2483; 1964 II, p. 2380; 1966 I, p. 1013; 1971 I, p. 1761).

"the 1966 regulations" means the Therapeutic Substances (Manufacture of Antibiotics) Regulations 1966, as amended (**a**);

"parenteral injection" in relation to any substance includes any administration of the substance by insertion into the body by any route other than that of the gastro-intestinal tract, but does not include any application of the substance to the skin.

Inclusion of tetracycline (non-parenteral) and oxytetracycline (non-parenteral) in Schedule 1 *to the Act*

2. Tetracycline (non-parenteral) and oxytetracycline (non-parenteral) are hereby added to Schedule 1 to the Act as being substances the purity or potency of which cannot be adequately tested by chemical means.

Amendment of the Therapeutic Substances (Manufacture of Antibiotics) Regulations 1966 *to* 1969

3. The Therapeutic Substances (Manufacture of Antibiotics) Regulations 1966, as amended, shall be further amended by adding after regulation 93 the following regulations—

PART XVIII

SPECIAL PROVISIONS RELATING TO TETRACYCLINE (NON-PARENTERAL) AND OXYTETRACYCLINE (NON-PARENTERAL)

Definitions and proper names

94. (*a*) "Tetracycline (non-parenteral)" is tetracycline as defined in regulation 23(1) and (3) of the 1966 regulations, preparations thereof and mixtures which include any of the foregoing, in each case when intended for application to the skin or for administration by means other than parenteral injection. Its proper name is "tetracycline (non-parenteral)".

(*b*) "Oxytetracycline (non-parenteral)" is oxytetracycline as defined in regulation 23(1) and (4) of the 1966 regulations, preparations thereof and mixtures which include any of the foregoing, in each case when intended for application to the skin or for administration by means other than parenteral injection. Its proper name is "oxytetracycline (non-parenteral)".

Exclusion of application of regulation 5(1) *and* (2) *of the General Regulations*

95. Regulation 5(1) and (2) of the general regulations (which relate to the sealing of containers and provision of a bacteriostatic) shall not apply to tetracycline (non-parenteral) and oxytetracycline (non-parenteral) except when intended for application to the eyes.

Exclusion of application of regulations 10 *and* 29 *of the* 1966 *regulations*

96. Regulations 10 and 29 of the 1966 regulations (which relate to tests for freedom from pyrogenic and histamine-like substances) shall not apply to tetracycline (non-parenteral) and oxytetracycline (non-parenteral).

(**a**) S.I. 1966/505, 1967/1195, 1968/906, 1969/1707 (1966 I, p. 1049; 1967 II, p. 3498; 1968 II, p. 2389; 1969 III, p. 5378).

Discretion of the licensing authority to require tests for sterility

97. Regulation 7 of the 1966 regulations (which relates to tests for sterility) shall only apply to tetracycline (non-parenteral) and oxytetracycline (non-parenteral) when intended for application to the eyes, or for any other application where the licensing authority is satisfied that a similar degree of risk of infection exists as in the case of an application to the eyes.

These regulations were made by the aforesaid Joint Committee on 27th May 1971.

Keith Joseph,
Peter Thomas,
Gordon Campbell,
W. K. Fitzsimmons,
Members of the Joint Committee.

L. H. Hayward,
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 to 1969 by adding tetracycline and oxytetracycline when intended for application to the skin or for administration by means other than parenteral injection, and modify the provisions relating to the sealing of containers and the provision of a bacteriostatic, tests for sterility and freedom from pyrogenic and histamine-like substances.