STATUTORY INSTRUMENTS

1964 No. 1076

THERAPEUTIC SUBSTANCES

The Therapeutic Substances (Manufacture and Importation) General (Amendment) Regulations 1964

Made - - - -	11*th July* 1964
Laid before Parliament	17*th July* 1964
Coming into Operation	20*th July* 1964

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 and Importation) General (Amendment) Regulations 1964, and shall come into operation on 20th July 1964.

(2) The Therapeutic Substances (Manufacture and Importation) General Regulations 1963(b) and these regulations may be cited together as the Therapeutic Substances (Manufacture and Importation) General Regulations 1963 and 1964.

(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.

Amendment of the Therapeutic Substances (Manufacture and Importation) General Regulations 1963

2. The Therapeutic Substances (Manufacture and Importation) General Regulations 1963 shall be amended as follows:—

(*a*) For paragraph 1(3) of schedule 2 (which relates to tests for sterility) there shall be substituted the following sub-paragraph—

"(3) In the case of every substance which is itself bactericidal or bacteriostatic, and of every preparation to which a bactericide or bacteriostatic has been added, either—

(*a*) there shall be added to the sample before it is tested—

(i) such a volume of medium as will dilute either the substance itself or the added bactericide or bacteriostatic so as to render it ineffective, or

(ii) such a substance in such concentration as will neutralise the bactericidal or bacteriostatic activity of the substance or preparation being tested without inhibiting the growth of micro-organisms; or

(a) 4 & 5 Eliz. 2. c. 25. (b) S.I. 1963/1450 (1963 II, p. 2483). (c) 52 & 53 Vict. c. 63.

(*b*) a solution of the sample shall be made and passed through a membrane filter with an average pore diameter not greater than 0·75 microns, the filter shall be suitably washed to remove bactericidal or bacteriostatic activity and the membrane shall then be tested in the manner prescribed by paragraph 2 of this schedule, but in that event the reference in sub-paragraph (2) thereof to the inoculation of specified quantities of the sample into a tube or other vessel containing the medium shall be construed as a reference to the placing of the whole membrane into such tube or vessel, and the provisions of sub-paragraph (3) thereof shall not apply." ;

(*b*) For paragraph 2(4) of schedule 2 (which prescribes the method of testing for sterility) there shall be substituted the following sub-paragraph—

"(4) The inoculated tubes or vessels shall be incubated between 30°C. and 32°C. for 7 days and examined during and after incubation, and durable records shall be kept of the results of the examination of each tube." ;

(*c*) In paragraph 3(ii) of schedule 2 for the words " 5 days ; " there shall be substituted the words " 7 days ; ".

These regulations were made by the aforesaid Joint Committee on 11th July 1964.

Anthony Barber,
Michael Noble,
Wm. J. Morgan,
Members of the Joint Committee.

Wilfred Turner,
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 make minor amendments in connection with sterility testing of therapeutic substances so as to bring the statutory requirements for such testing into conformity with recent advances in manufacturing practice.