STATUTORY INSTRUMENTS

1964 No. 1434

THERAPEUTIC SUBSTANCES

The Therapeutic Substances (Manufacture of Vaccines, Toxins and Antigens) Amendment Regulations 1964

Made - - - -	*7th September* 1964
Laid before Parliament	*15th September* 1964
Coming into Operation	*16th September* 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 section 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 Vaccines, Toxins and Antigens) Amendment Regulations 1964, and shall come into operation on 16th September 1964.

(2) The Therapeutic Substances (Manufacture of Vaccines, Toxins and Antigens) Regulations 1963(b) and these regulations may be cited together as the Therapeutic Substances (Manufacture of Vaccines, Toxins and Antigens) 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 of Vaccines, Toxins and Antigens) Regulations 1963

2. The Therapeutic Substances (Manufacture of Vaccines, Toxins and Antigens) Regulations 1963 shall be amended as follows :—

(*a*) For regulation 4 (Tests of combined antigens) there shall be substituted the following regulation—

> "4. Where antigens are combined in a single vaccine the vaccine in its combined form shall satisfy the tests for potency and toxicity prescribed by these regulations for each substance included in the combination and shall conform in other respects to the standards prescribed by the general regulations and these regulations for each such substance." ;

(*b*) In regulation 5 (which relates to tests on guinea-pigs) after "XVIII" there shall be inserted the words "or parts XXIII to XXV" ;

(*c*) At the end of regulation 19 (which relates to the testing of B.C.G. vaccine) there shall be added the following paragraph—

> "(6) When dried B.C.G. vaccine intended for other than intracutaneous injection is reconstituted for testing in accordance with regulations 22, 23 and 24 of these regulations, the reconstituted

(a) 4 & 5 Eliz. 2. c. 25. (b) S.I. 1963/1459 (1963 II, p. 2561).
(c) 52 & 53 Vict. c. 63.

vaccine shall be diluted to a strength corresponding to the strength of a dried vaccine, made from an identical strain of B.C.G. and intended for intracutaneous injection, when being tested under these regulations." ;

(*d*) After regulation 122 there shall be added the following regulations—

" PART XXIII

SPECIAL PROVISIONS RELATING TO DIPHTHERIA AND PERTUSSIS VACCINE

Definition and proper name

123. Diphtheria and pertussis vaccine is a mixture of diphtheria vaccine F.T. and pertussis vaccine. The proper name of the substance in the form of a simple suspension is " diphtheria and pertussis vaccine " and in any form other than that of a simple suspension is " diphtheria and pertussis vaccine " together with a phrase indicating the nature of the additional process to which it has been subjected, e.g. " diphtheria and pertussis vaccine containing aluminium hydroxide or aluminium phosphate ".

Tests for potency

124.—(1) Diphtheria and pertussis vaccine shall be tested for potency as prescribed for diphtheria vaccine F.T. in regulation 49 of these regulations, and for pertussis vaccine in regulation 113 of these regulations.

(2) Diphtheria and pertussis vaccine containing aluminium hydroxide or aluminium phosphate shall be tested for potency as prescribed for diphtheria vaccine A.P.T. in regulation 52 of these regulations, and for pertussis vaccine in regulation 113 of these regulations.

Test for specific toxicity

125. A quantity of diphtheria and pertussis vaccine equivalent to the dose required by regulation 6(3) of these regulations to be stated on the container shall be injected subcutaneously or intraperitoneally into each of not less than 5 guinea-pigs. The injection shall not cause the death from specific diphtheria toxaemia of any of the guinea-pigs within 30 days.

PART XXIV

SPECIAL PROVISIONS RELATING TO DIPHTHERIA AND TETANUS VACCINE

Definition and proper name

126. Diphtheria and tetanus vaccine is a mixture of diphtheria vaccine F.T. and tetanus vaccine. The proper name of the substance in the form of a simple solution is " diphtheria and tetanus vaccine " and in any form other than that of a simple solution is " diphtheria and tetanus vaccine " together with a phrase indicating the nature of the additional process to which it has been subjected, e.g., " diphtheria and tetanus vaccine containing aluminium hydroxide or aluminium phosphate ".

Tests for potency as an immunising antigen

127.—(1) Diphtheria and tetanus vaccine shall be tested for potency as prescribed for diphtheria vaccine F.T. in regulation 49 of these regulations, and for tetanus vaccine in regulation 67(*c*) of these regulations.

(2) Diphtheria and tetanus vaccine containing aluminium hydroxide or aluminium phosphate shall be tested for potency as prescribed for diphtheria vaccine A.P.T. in regulation 52 of these regulations, and for tetanus vaccine in regulation 68(3) of these regulations.

Tests for specific toxicity

128.—(1) A quantity of diphtheria and tetanus vaccine equivalent to 5 times the dose required by regulation 6(3) of these regulations to be stated on the container shall be injected subcutaneously or intraperitoneally into each of not less than 5 guinea-pigs. The injection shall not cause the death from specific diphtheria toxaemia of any of the guinea-pigs within 30 days, or produce any symptoms of tetanus in any of the guinea-pigs within 30 days.

(2) A quantity of diphtheria and tetanus vaccine containing aluminium hydroxide or aluminium phosphate equivalent to the dose required by regulation 6(3) of these regulations to be stated on the container shall be injected subcutaneously or intraperitoneally into each of not less than 5 guinea-pigs. The injection shall not cause the death from specific diphtheria toxaemia of any of the guinea-pigs within 30 days, or produce any symptoms of tetanus in any of the guinea-pigs within 30 days.

PART XXV

SPECIAL PROVISIONS RELATING TO DIPHTHERIA, TETANUS AND PERTUSSIS VACCINE

Definition and proper name

129. Diphtheria, tetanus and pertussis vaccine is a mixture of diphtheria vaccine F.T., tetanus vaccine and pertussis vaccine. The proper name of the substance in the form of a simple suspension is " diphtheria, tetanus and pertussis vaccine " and in any form other than that of a simple suspension is " diphtheria, tetanus and pertussis vaccine " together with a phrase indicating the nature of the additional process to which it has been subjected, e.g., " diphtheria, tetanus and pertussis vaccine containing aluminium hydroxide or alumininum phosphate ".

Tests for potency

130.—(1) Diphtheria, tetanus and pertussis vaccine shall be tested for potency as prescribed for diphtheria vaccine F.T. in regulation 49 of these regulations, for tetanus vaccine in regulation 67(*c*) of these regulations, and for pertussis vaccine in regulation 113 of these regulations.

(2) Diphtheria, tetanus and pertussis vaccine containing aluminium hydroxide or aluminium phosphate shall be tested for potency as prescribed for diphtheria vaccine A.P.T. in regulation 52 of these regulations, for tetanus vaccine in regulation 68(3) of these regulations, and for pertussis vaccine in regulation 113 of these regulations

Test for specific toxicity

131. A quantity of diphtheria, tetanus and pertussis vaccine equivalent to the dose required by regulation 6(3) of these regulations to be stated on the container shall be injected subcutaneously or intraperitoneally into each of not less than 5 guinea-pigs. The injection shall not cause death from specific diphtheria toxaemia of any of the guinea-pigs within 30 days or produce any symptoms of tetanus in any of the guinea-pigs within 30 days.".

These regulations were made by the aforesaid Joint Committee on 7th September 1964.

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

W. 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 extend the provisions of the Therapeutic Substances (Manufacture of Vaccines, Toxins and Antigens) Regulations 1963 to make special provisions for combined diphtheria, tetanus and pertussis vaccines, including provisions for testing their potency and freedom from toxicity.