1964 No. 1077

THERAPEUTIC SUBSTANCES

The Therapeutic Substances (Manufacture of Sera and Antitoxins) 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 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 Sera and Antitoxins) Amendment Regulations 1964, and shall come into operation on 20th July 1964.

(2) The Therapeutic Substances (Manufacture of Sera and Antitoxins) Regulations 1963(b) and these regulations may be cited together as the Therapeutic Substances (Manufacture of Sera and Antitoxins) 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 Sera and Antitoxins) Regulations 1963

2. The Therapeutic Substances (Manufacture of Sera and Antitoxins) Regulations 1963 shall be amended as follows:—

(*a*) After regulation 41 there shall be inserted the following regulations:—

"PART XI

SPECIAL PROVISIONS RELATING TO MIXED GAS GANGRENE ANTITOXIN

Definition and proper name

42. Mixed gas gangrene antitoxin is a mixture of the antitoxic globulins, or derivatives thereof, of gas gangrene antitoxin (Welchii), gas gangrene antitoxin (septicum) and gas gangrene antitoxin (oedematiens), which are respectively defined in regulations 30, 34 and 38 of these regulations. Its proper name is "mixed gas gangrene antitoxin".

Strength

43. A solution of mixed gas gangrene antitoxin which has a potency of less than 1,000 units per millilitre of gas gangrene antitoxin (Welchii), 500 units per millilitre of gas gangrene antitoxin (septicum) and 1,000 units per millilitre of gas gangrene antitoxin (oedematiens) shall not be issued.

(a) 4 & 5 Eliz. 2. c. 25. (b) S.I. 1963/1457 (1963 II, p. 2548).
(c) 52 & 53 Vict. c. 63.

Quality

44. A solution of the antitoxic globulins, or of derivatives thereof, shall not contain more than 0·1 gramme of solid matter for each volume of the mixture comprising 500 units of gas gangrene antitoxin (Welchii), 250 units of gas gangrene antitoxin (septicum) and 500 units of gas gangrene antitoxin (oedematiens)."

(*b*) The existing part XI (Special Provisions relating to Staphylococcus Antitoxin) and the existing regulations 42 and 43 shall be renumbered XII, 45 and 46 respectively.

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 extend the provisions of the Therapeutic Substances (Manufacture of Sera and Antitoxins) Regulations 1963 to mixed gas gangrene antitoxin, made up of the single gas gangrene antitoxins mentioned in parts VIII, IX and X of those regulations, and make special provisions relating to the mixed antitoxin.