1966 No. 504

THERAPEUTIC SUBSTANCES

The Therapeutic Substances (Manufacture of Vaccines, Toxins and Antigens) Amendment Regulations 1966

Made - - - -	*27th April* 1966
Laid before Parliament	*5th May* 1966
Coming into Operation	*1st June* 1966

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 Vaccines, Toxins and Antigens) Amendment Regulations 1966 and shall come into operation on 1st June 1966.

(2) The Therapeutic Substances (Manufacture of Vaccines, Toxins and Antigens) Regulations 1963 to 1965(b) and these regulations may be cited together as the Therapeutic Substances (Manufacture of Vaccines, Toxins and Antigens) Regulations 1963 to 1966.

(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, as amended, (hereinafter referred to as "the principal regulations"), shall be further amended as follows:—

(*a*) for regulation 6 (which relates to labelling) there shall be substituted the following regulation—

"**6.**—(1) Subject to the provisions of paragraph (2) of this regulation—

(*a*) the particulars specified in regulation 6(1)(*a*), (*b*) and (*c*) of the general regulations shall be borne by the container of any substance to which these regulations relate;

(a) 4 & 5 Eliz. 2. c. 25.
(b) S.I. 1963/1459, 1964/1434, 1965/1005 (1963 II, p. 2561; 1964 III p. 3324; 1965 I, p. 2454).
(c) 52 & 53 Vict. c. 63.

(*b*) the particulars specified in sub-paragraphs (*e*), (*f*) and (*i*) of the said regulation 6(1) shall be borne either by the container of any such substance or by the package in which it is offered for sale;

(*c*) in addition to the particulars required by sub-paragraph (*a*) of this paragraph, a statement of the proper dose for administration at one time into a human subject shall be borne by the container of any such substance.

(2) Where by any provision of these regulations any particulars are required to be borne by the container of any substance to which these regulations relate and such container is of a capacity of less than 2·5 millilitres, such particulars may, with the consent of the licensing authority, be borne instead by the package in which the container is offered for sale." ;

(*b*) regulations 14, 26, 75, 79, 109, 122 and 163 of the principal regulations (which relate to labelling) shall have effect subject to the exception in regulation 6(2) of those regulations, as amended by the last foregoing paragraph, for containers of a capacity of less than 2·5 millilitres and, in the said regulations and in regulations 37, 46, 65, 69, 94, 143 and 155 of the principal regulations, references to regulation 6(1)(*a*), (*b*) and (*c*) of the principal regulations shall be substituted for references to regulation 6(1), (2) and (3) respectively;

(*c*) for regulations 36(2) and (4) (which relate to tests for potency of smallpox vaccine) there shall be substituted the following:—

" (2) The vaccine shall be tested—

(*a*) by the enumeration of pock-forming units after application of the vaccine to the chorio-allantoic membranes of chick embryos in the manner described in paragraph (4) of this regulation, or in that manner with such modifications as may be approved by the licensing authority; or

(*b*) on material of such other kind, and in such manner, as may be approved by the licensing authority." ; and

" (4) For the test on the chorio-allantoic membranes of chick embryos, at least ten chick embryos, each of about 12 days' incubation, shall be divided into two equal groups. To the chorio-allantoic membrane of each embryo of the first group, 0·1 millilitre or 0·2 millilitre of a suitable dilution of the vaccine shall be applied. To the chorio-allantoic membrane of each embryo of the second group, 0·1 millilitre or 0·2 millilitre of another suitable dilution of the vaccine shall be applied. After the optimum time of incubation, the total number of discrete specific lesions shall be counted on the membrane of each embryo. The dilutions shall be so chosen that the membranes of at least one of the groups yield countable numbers of lesions exceeding ten per membrane. From the number of lesions counted in this group and from the dilutions and volumes used, the number of pock-forming units in 1 millilitre of the undiluted vaccine shall be computed, and the vaccine shall pass the test if the number thus computed is not less than the number computed when a freeze-dried reference preparation held by the National Institute for Medical Research, London, is subjected at the same time to a similar test." ;

(*d*) in regulation 113 (which relates to the test for potency as an immunising agent of pertussis vaccine), for the second sentence there shall be substituted—

"The pertussis vaccine, diluted if necessary so that one human dose is contained in 1 millilitre, shall be accepted as sufficiently potent if the test shows that its potency is at least equal to that of the standard preparation when the latter is reconstituted to contain 20×10^9 organisms per millilitre.".

These regulations were made by the aforesaid joint Committee on 27th April 1966.

Kenneth Robinson,
William Ross,
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.*)

These regulations, made under Part I of the Therapeutic Substances Act 1956, amend the provisions of the Therapeutic Substances (Manufacture of Vaccines, Toxins and Antigens) Regulations 1963 to 1965 relating to the testing for potency of smallpox vaccine and to the testing for potency as an immunising agent of pertussis vaccine.

They also amend the provisions relating to labelling for containers of less than 2·5 millilitres capacity.