STATUTORY INSTRUMENTS

1967 No. 1196

THERAPEUTIC SUBSTANCES

The Therapeutic Substances (Manufacture of Vaccines, Toxins and Antigens) Amendment Regulations 1967

Made - - -	*4th August* 1967
Laid before Parliament	*11th August* 1967
Coming into Operation	*1st September* 1967

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 1967 and shall come into operation on 1st September 1967.

(2) The Therapeutic Substances (Manufacture of Vaccines, Toxins and Antigens) Regulations 1963 to 1966(b) and these regulations may be cited together as the Therapeutic Substances (Manufacture of Vaccines, Toxins and Antigens) Regulations 1963 to 1967.

(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 (d), shall be further amended as follows:—

(*a*) In regulation 5 (which relates to tests on guinea-pigs) for "XXVIII" there shall be substituted "XXIX";

(*b*) after regulation 163 there shall be added the following regulations—

(a) 4 & 5 Eliz. 2. c. 25.
(b) S.I. 1963/1459, 1964/1434, 1965/1005, 1966/504 (1963 II, p.2561; 1964 III, p.3324; 1965 I, p.2454; 1966 I, p.1046).
(c) 52 & 53 Vict. c. 63.
(d) The relevant amending instruments are S. I. 1965/1005 and 1966/504 (1965 I, p. 2454; 1966 I, p.1046).

"PART XXIX

PROVISIONS RELATING TO THERAPEUTIC ALLERGENS

Definition and proper name

164. A therapeutic allergen is an antigen prepared from material to which human subjects may be hypersensitive, such material in this part of these regulations being referred to as "source material". A therapeutic allergen is intended for use in the treatment of hypersensitive human subjects. The proper name of any therapeutic allergen shall include an indication of the nature of the source material from which that allergen has been prepared.

Staff of establishment

165. The establishment in which any therapeutic allergen is prepared shall be under the complete direction and control of an expert approved by the licensing authority.

Identity of source materials

166. Source materials used in the preparation of therapeutic allergens shall, before being subjected to any process, be tested for identity by tests approved by the licensing authority. The records which the licensee is required by regulation 4 of the general regulations to keep shall include a record of the origin, properties and characters of the materials.

Precautions to be observed in preparation of allergens

167.—(1) The process by which any therapeutic allergen is prepared shall be approved by the licensing authority.

(2) Where the process by which any therapeutic allergen is prepared involves the use of pyridine, that allergen shall not contain in its final form more than 25 micrograms of residual pyridine per millilitre.

(3) The licensee shall take all reasonably practicable precautions to prevent the accidental mixing of allergens from different source materials.

Allergen content

168. The concentration of any therapeutic allergen shall be expressed either as protein nitrogen content or as a percentage by volume of purified antigen.

Tests of allergens

169.—(1) Every therapeutic allergen shall be subjected to the following tests and shall not be issued unless it passes all such tests:—

(*a*) *Tests for freedom from abnormal toxicity*

(i) 0.5 millilitre of the highest concentration of the allergen intended for issue shall be injected intraperitoneally into each of 5 healthy mice each weighing between 17 and 22 grams. None of the animals shall show signs of ill health for the 7 days following the inoculation. At the end of this period the animals shall be killed and on examination none shall show visible lesions of the peritoneum. Where not more than one of the mice shows such signs of ill health or such lesions, then the test may be carried out on five other such mice, and the sample shall be regarded as free from abnormal toxicity if none of those mice shows such signs within the said period, or such lesions after death.

(ii) 0.1 millilitre of the highest concentration of the allergen intended for issue shall be injected intradermally into each of 2 guinea-pigs neither of which shall show signs of necrosis at the place of injection during the 7 days following the inoculation.

(*b*) *Tests for sterility*

In addition to being tested for sterility in accordance with the general regulations, therapeutic allergens shall be tested for mycoplasmal contamination in liquid and on solid media which have been shown to be capable of detecting mycoplasmata.

(2) For the purposes of the tests prescribed in paragraph (1)(*a*) of this regulation a therapeutic allergen contained in glycerin may be diluted in four times its volume of physiological saline or to such an extent that the test dose contains not more than 10 per cent v/v glycerin before injection.

Adsorbed allergens

170.—(1) Therapeutic allergens adsorbed on aluminium hydroxide shall not be issued with a pH value greater than 7.0.

(2) The adsorbing agent used for the preparation of adsorbed therapeutic allergens shall be such as shall be approved by the licensing authority.

(3) In addition to the requirements of regulations 167 and 169 of these regulations, adsorbed therapeutic allergens shall be tested by methods approved by the licensing authority to show the extent to which free allergens are present in the supernatant fluid.

Oil adjuvant allergens

171. The oil and the emulsifying agent used for the preparation of oil adjuvant therapeutic allergens shall be such as shall be approved by the licensing authority.

Labelling

172. In addition to the particulars required by regulation 6 (1)(*b*) of these regulations the package in which a container of any therapeutic allergen is offered for sale shall bear the particulars specified in regulation 6(1)(*g*) and (*h*) of the general regulations.".

These regulations were made by the aforesaid Joint Committee on 4th August 1967.

Kenneth Robinson,
William Ross,
Wm. J. Morgan,
Members of the Joint Committee.

W. F. Farrant,
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 Vaccines, Toxins and Antigens) Regulations 1963 to 1966 to make special provisions for therapeutic allergens, including provisions for their definition and method of preparation, and for testing their sterility and freedom from toxicity.