THE SCHEDULE

Distance between the local exchange and the terminal exchange	(i) For the first three minutes or part of three minutes: (ii) For each complete period of three minutes after the first: (iii) For any odd period of more than two minutes:	For any odd period of one minute or less:	For any odd period of more than one minute but not more than two minutes:
	s. d.	s. d.	s. d.
(*a*) More than 75 miles but not more than 125 miles ...	3 0	1 0	2 0
(*b*) More than 125 miles ...	3 9	1 3	2 6

EXPLANATORY NOTE

(This Note is not part of the Regulations, but is intended to indicate their general purport.)

These Regulations replace the Telephone (Channel Islands) Regulations 1952.

The main changes are:

(*a*) The Regulations no longer apply to calls in either direction between the Jersey and the Guernsey telephone systems;

(*b*) Provision is made for fixed time calls and personal calls to other parts of the British Islands, for transferred charge calls to and from other parts of the British Islands, and for a charge for advising a subscriber of the duration of, or charge for, a call.

THERAPEUTIC SUBSTANCES

1956 No. 1131

The Therapeutic Substances Amendment Regulations, 1956

Made - - - -	23*rd July*, 1956
Laid before Parliament	30*th July*, 1956
Coming into Operation	1*st August*, 1956

The Joint Committee constituted by subsection (1) of section 4 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 subsection (2) of the said section 4, hereby make the following regulations:—

1.—(1) These regulations may be cited as the Therapeutic Substances Amendment Regulations, 1956, and shall come into operation on the first day of August, 1956.

(**a**) 4 & 5 Eliz. 2. c. 25.

(2) The Therapeutic Substances Regulations, 1952 to 1954, and these regulations may be cited together as the Therapeutic Substances Regulations, 1952 to 1956.

2. The provisions contained in the schedule to these regulations shall be inserted at the end of the third schedule to the Therapeutic Substances Regulations, 1952(a).

SCHEDULE

"PART XVII

PROVISIONS APPLICABLE TO INACTIVATED POLIOMYELITIS VACCINE

Definition and proper name

1. This part of this schedule applies to any inactivated vaccine prepared from the poliomyelitis virus. The proper name of any such vaccine is "poliomyelitis vaccine".

Strains of poliomyelitis virus

2. The strains of poliomyelitis virus used for preparation of poliomyelitis vaccine shall be such as shall be approved by the licensing authority.

Staff of establishment

3. The establishment in which poliomyelitis vaccine is prepared shall be under the complete direction and control of an expert.

Production records

4. The licensee shall forward to the licensing authority full protocols of all batches of vaccine, including batches the manufacture of which the licensee does not complete, whether the batch passes or fails any of the tests laid down in the subsequent provisions of this part of this schedule.

Provisions as to tissue for production of poliomyelitis virus

5.—(1) The tissue used for the production of poliomyelitis virus shall be the kidney tissue of healthy cynomolgus or rhesus monkeys or of monkeys of other suitable species.

(2) The kidney of a monkey shall not be used for this purpose—

(*a*) unless the monkey has reacted negatively to tuberculin during the preceding 2 weeks; or

(*b*) if the monkey has previously been used for any experimental purpose; or

(*c*) if on post-mortem examination under the supervision of a qualified pathologist any significant gross pathological lesion is revealed:

Provided that if the only experimental purpose for which a monkey has been used is the tests required by paragraph 11 or paragraph 12 of this part of this schedule, its kidney may be used if since the beginning of those tests it has shown no clinical abnormality.

Method of producing virus suspension

6.—(1) Poliomyelitis virus for preparing poliomyelitis vaccine shall be grown with aseptic techniques in tissue cultures containing—

(*a*) a suitable nutrient fluid;

(*b*) viable cells, trypsinised or non-trypsinised, from the kidneys of monkeys;

(a) S.I. 1952/1937 (1952 III, p. 3420).

(*c*) suitable antibiotics in the smallest effective concentration ; and

(*d*) if the licensee desires, phenol red in a concentration not exceeding 0·002 per cent.:

Provided that if penicillin or streptomycin is used as the antibiotic not more than 200 units per millilitre shall be used.

(2) No extraneous protein which is capable of producing allergic effects on injection into human subjects (such as embryonic extracts which have not been subjected to ultrafiltration, and animal serum) shall be added to the tissue cultures prepared as aforesaid, and if animal serum is used at any stage in the manufacture, it shall not be used in such quantity that the final medium will contain more than one part of animal serum in 1 million.

(3) The virus suspension shall be filtered at suitable intervals by a suitable method.

(4) The total volume of the virus suspension shall not exceed 50 litres.

Tests of virus suspension

7.—(1) After filtration the virus suspension shall be tested by a suitable method to determine the minimum infective dose for a tissue culture ; and it shall not be used in the next stage of the preparation of poliomyelitis vaccine unless it contains at least 1 million such doses per millilitre.

(2) The suspension shall also be tested by a suitable method for the presence of B virus and of *Mycobacterium tuberculosis.*

(3) When, in the opinion of the licensing authority, a suspension is ready for testing to determine whether the strain of virus which it contains is attenuated, the suspension shall be tested for attenuation by suitable methods.

Method of inactivating virus suspension

8.—(1) All virus infectivity in the virus suspension shall be destroyed by a suitable method, by the use of formaldehyde or by some other means approved by the licensing authority.

(2) The course of the inactivation procedure shall be checked from time to time by suitable methods, and the minimum period of inactivation shall be estimated from the results of these checks.

Tests for inactivation

9.—(1) When the minimum period of inactivation has been estimated in relation to a virus suspension, a sample of 500 millilitres of the suspension shall be withdrawn by a suitable method 3 days before the end of that period, and a further similar sample shall be withdrawn at the end of that period. Each sample shall be tested by suitable methods for the presence of active virus.

(2) The suspension shall be regarded as inactivated if neither sample is shown to contain active virus. If the sample withdrawn at the end of the period of inactivation does not, but the sample withdrawn 3 days before the end of that period does, contain active virus the suspension may be subjected to inactivation in accordance with the last preceding paragraph for a further 3 days. The suspension shall be regarded as inactivated if at the end of that period a further sample of 500 millilitres, withdrawn and tested in the same way as the other samples, contains no active virus.

Preparation of vaccine

10.—(1) Poliomyelitis vaccine shall be made by mixing inactivated suspensions of poliomyelitis virus of types 1, 2 and 3 in approximately equal proportions.

(2) Samples of each batch of such vaccine as finally mixed shall be withdrawn and tested in accordance with the next two following paragraphs before the filling of containers and before the addition of a bacteriostatic. If the licensing authority so require, portions of these samples shall be made available to the licensing authority.

Tests for safety of vaccine

11.—(1) A sample of at least 1,500 millilitres of the vaccine shall be tested by suitable methods for the presence of active virus.

(2) The vaccine shall also be tested for the presence of active virus, by suitable methods by inoculation into suitable monkeys:

Provided that the provisions of this sub-paragraph shall not apply to vaccine in which each of the three virus suspensions was made from strains shown, by testing in accordance with sub-paragraph (3) of paragraph 7 of this part of this schedule, to be attenuated.

(3) The vaccine shall also be tested for the presence of LCM virus by a suitable method.

(4) The vaccine shall not be issued for sale if it fails to pass any of the tests required by this paragraph.

Tests for antigenicity of vaccine

12. The vaccine shall be tested in a suitable species of animal, by suitable methods for its power of producing antibodies to all three types of poliomyelitis virus.

Certificate of licensing authority as to passing of safety tests

13. The licensee shall not issue any batch of poliomyelitis vaccine for sale unless it has been certified by the licensing authority to have passed the tests contained in this part of this schedule.

Bacteriostatic

14. If poliomyelitis vaccine is issued in multidose containers, the bacteriostatic added shall be one which, at the concentration used, prevents the growth of micro-organisms and does not cause any loss of potency of the vaccine before the date after which the vaccine may not be used.

Labelling

15. The label on a container of poliomyelitis vaccine shall state:—

(*a*) the date after which the preparation may not be used;

(*b*) the precautions necessary for preserving the properties of the contents until that date;

(*c*) in the case of a multidose container, the nature of the bacteriostatic;

(*d*) the proper dose for administration at one injection into a human subject.

Method of issue

16. Poliomyelitis vaccine shall not be issued for sale combined with any other material without the consent of the licensing authority."

These regulations were made by the aforesaid Joint Committee this twenty-third day of July, nineteen hundred and fifty-six.

Robert H. Turton,
James Stuart,
Dehra Parker,
Members of the Joint Committee.

W. G. Honnor,
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 contain provisions as to the method of manufacture of inactivated poliomyelitis vaccine and as to the tests for safety and efficacy to be applied to it.

1956 No. 346

The Therapeutic Substances (Control of Sale and Supply) Regulations, 1956

Made - - - -	8*th March*, 1956
Laid before Parliament	15*th March*, 1956
Coming into Operation	31*st March*, 1956

Whereas the substances hereinafter mentioned appear to the Minister of Health, the Secretary of State and the Minister of Health and Local Government for Northern Ireland (hereinafter called "the Ministers") to be substances which are capable of causing danger to the health of the community if used without proper safeguards:

Now, therefore, the Ministers, in exercise of the powers conferred on them by subsection (1) of section 2 of the Penicillin Act, 1947(**a**), as enacted in subsection (1) of section 1 of the Therapeutic Substances (Prevention of Misuse) Act, 1953(**b**), and of all other powers enabling them in that behalf, jointly, after consultation with the Medical Research Council, hereby make the following regulations:—

1.—(1) These regulations may be cited as the Therapeutic Substances (Control of Sale and Supply) Regulations, 1956, and shall come into operation on the thirty-first day of March, 1956.

(2) The Interpretation Act, 1889(**c**), applies to the interpretation of these regulations as it applies to the interpretation of an Act of Parliament.

2. The Penicillin Act, 1947, as amended by subsequent enactments(**d**), shall apply—

(*a*) to bacitracin, that is to say, the antimicrobial polypeptides produced by certain strains of *Bacillus licheniformis* and by *Bacillus subtilis var. Tracey*, which contain the amino-acids L-cysteine, D-glutamic acid, L-histidine, L-*iso*leucine, L-leucine, L-lysine, D-ornithine, D-phenylalanine and DL-aspartic acid;

(*b*) to tetracycline and salts thereof;

(*c*) to viomycin, that is to say, any antimicrobial substance produced by *Streptomyces griseus var. purpureus*, and to any salt of viomycin;

(**a**) 10 & 11 Geo. 6. c. 29.
(**b**) 1 & 2 Eliz. 2. c. 32.
(**c**) 52 & 53 Vict. c. 63.
(**d**) 14 & 15 Geo. 6. c. 13; 1 & 2 Eliz. 2. c. 32.