STATUTORY INSTRUMENTS

1968 No. 907

THERAPEUTIC SUBSTANCES

The Therapeutic Substances (Manufacture of Hormone Products) Amendment Regulations 1968

Made - - -	10*th June* 1968
Laid before Parliament	17*th June* 1968
Coming into Operation	1*st July* 1968

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 Hormone Products) Amendment Regulations 1968, and shall come into operation on 1st July 1968.

(2) The Therapeutic Substances (Manufacture of Hormone Products) Regulations 1966(**b**) and these regulations may be cited together as the Therapeutic Substances (Manufacture of Hormone Products) Regulations 1966 and 1968.

(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.

Inclusion of substances in schedule to Act

2. Follicle stimulating hormone and preparations thereof are hereby added to schedule 1 to the Act as being substances the purity or potency of which cannot be adequately tested by chemical means.

Amendment of the Therapeutic Substances (Manufacture of Hormone Products) Regulations 1966

3. The Therapeutic Substances (Manufacture of Hormone Products) Regulations 1966 shall be amended by adding, after regulation 78, the following regulations :—

PART XXI

GENERAL PROVISIONS RELATING TO FOLLICLE STIMULATING HORMONE AND PREPARATIONS THEREOF

Definition and proper name

79.—(1) Follicle stimulating hormone is an extract of human post-menopausal urine containing primarily that hormone which has the property of stimulating growth and maturation of germinal follicles in the ovary. Such extract may contain substances with interstitial cell stimulating hormone activity.

(**a**) 1956 c. 25. (**b**) S.I. 1966/502 (1966 I, p. 1025). (**c**) 1889 c. 63.

(2) The proper name of follicle stimulating hormone is "follicle stimulating hormone", and the proper names of preparations of follicle stimulating hormone shall be such as the licensing authority may approve.

Preparation

80. The methods by which follicle stimulating hormone shall be obtained from the urine of post-menopausal women shall be such as the licensing authority may approve.

Standard preparations

81.—(1) The standard preparation of follicle stimulating hormone is one of dried follicle stimulating hormone kept at the National Institute for Medical Research, London.

(2) The standard preparation for use in determining interstitial cell stimulating hormone activity is one kept at the National Institute for Medical Research, London.

Units of standardisation

82. The unit of follicle stimulating hormone activity and the unit of interstitial cell stimulating hormone activity for the purpose of these regulations is the specific activity contained in such an amount of the appropriate standard preparation as is for the time being indicated by the licensing authority, on the advice of the Medical Research Council, as the quantity exactly equivalent to the unit accepted for international use.

Strength

83.—(1) Follicle stimulating hormone in solid form shall not be issued with a potency of less than 10 units per milligram.

(2) The potency of follicle stimulating hormone shall be determined by a method approved by the licensing authority as suitable for determining specific follicle stimulating hormone activity. Such activity shall lie between 80 per cent.. and 125 per cent. of the activity stated by the manufacturer, and the fiducial limits of error (P=0.95) shall lie between 64 per cent. and 156 per cent. of the activity so stated.

Tests for sterility

84. Follicle stimulating hormone and preparations thereof shall be tested for sterility in accordance with the general regulations.

Test for freedom from abnormal toxicity

85.—(1) Follicle stimulating hormone and preparations thereof shall be tested for freedom from abnormal toxicity in accordance with this regulation.

(2) A solution containing not less than 50 units of follicle stimulating hormone in not more than 0.5 millilitre of physiological saline shall be injected intravenously over a period of time not exceeding one minute into each of 5 healthy mice, each weighing between 17 and 22 grams. The material shall pass the test either if none of the mice die within 48 hours after the injection, or if only one of the mice dies within that period and, after similar injections have been made into 5 other such mice, none of those mice dies within 48 hours after the injection.

Assay of interstitial cell stimulating hormone activity

86. Follicle stimulating hormone and preparations thereof shall, if the licensing authority so require, be subjected to tests approved by such authority as suitable for determining specific interstitial cell stimulating hormone activity, and such activity and the fiducial limits of error thereof shall be calculated from the results of the tests. The estimated activity shall lie between 80 per cent. and 125 per cent. of the activity stated by the manufacturer and the fiducial limits of error (P=0.95) shall lie between 64 per cent. and 156 per cent. of the activity so stated.

Labelling

87. In addition to the particulars required by regulation 4(1)(*a*) and (*b*) of these regulations, the following particulars shall be borne by the container of follicle stimulating hormone or of preparations thereof :—

(*a*) the number of units of follicle stimulating hormone activity in the container, and

(*b*) if the licensing authority so require, the estimated number of units of interstitial cell stimulating hormone activity in the container together with the total weight or volume of the contents of the container.

PART XXII

SPECIAL PROVISIONS RELATING TO FOLLICLE STIMULATING HORMONE AND PREPARATIONS THEREOF INTENDED FOR PARENTERAL INJECTION

Preparation

88. Follicle stimulating hormone and preparations thereof intended for parenteral injection shall be prepared from follicle stimulating hormone complying with the preceding part of these regulations.

Quality

89. Follicle stimulating hormone and preparations thereof intended for parenteral injection shall—

(*a*) contain proteins of human origin only ;

(*b*) have a pH value lying between 6.0 and 8.0 ;

(*c*) when in the dry form lose not more than 5.0 per cent. in weight when dried over phosphorus pentoxide for a period of 24 hours at a temperature between 20°C and 25°C and at a pressure not exceeding 0.02 millimetre of mercury.

Freedom from pyrogenic substances

90.—(1) Follicle stimulating hormone and preparations thereof intended for parenteral injection shall, if the licensing authority so require, be tested for freedom from pyrogenic substances in accordance with the general regulations and, in any event, shall be free from such substances to such an extent that, if so tested, they would pass the test.

(2) The number of units of follicle stimulating hormone and preparations thereof intended for parenteral injection for the purpose of the test for freedom from pyrogenic substances shall be not less than 1.0 unit per kilogram of the weight of each rabbit used in the test.

Labelling

91. In addition to the particulars required by regulation 4(1)(*b*) and (*c*) of these regulations a statement regarding the route of administration shall also be borne by the package in which a container of follicle stimulating hormone or preparation thereof intended for parenteral injection is offered for sale.".

These regulations were made by the aforesaid Joint Committee on 10th June 1968.

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, add follicle stimulating hormone and preparations thereof to the list of substances included in schedule 1 to the Act as being substances the purity or potency of which cannot be adequately tested by chemical means.

The regulations also amend the Therapeutic Substances (Manufacture of Hormone Products) Regulations 1966 by prescribing standards of purity and potency and labelling requirements for the added substances.