STATUTORY INSTRUMENTS

1966 No. 498

THERAPEUTIC SUBSTANCES

The Therapeutic Substances (Manufacture and Importation) General (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 and Importation) General (Amendment) Regulations 1966, and shall come into operation on 1st June 1966.

(2) The Therapeutic Substances (Manufacture and Importation) General Regulations 1963 and 1964(b) and these regulations may be cited together as the Therapeutic Substances (Manufacture and Importation) General 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 and Importation) General Regulations 1963

2. The Therapeutic Substances (Manufacture and Importation) General Regulations 1963, as amended, shall be further amended as follows:—

(*a*) for regulation 5 (1) (which relates to the sterility of containers) there shall be substituted the following—

"**5.**—(1) Every therapeutic substance sold or offered for sale shall, except as otherwise provided by the relative regulations, be effectively sealed in a sterilised container by a method sufficient to preclude the access of micro-organisms to the container, and the seal and the container shall be of materials which the licensing authority is satisfied are inert towards the contents of the container and sufficient to preclude the access of micro-organisms to those contents.";

(*b*) in regulation 11 (which relates to the undertaking required from the manufacturer of an imported substance) paragraph (*a*) shall be deleted.

(a) 4 & 5 Eliz. 2. c. 25. (b) S.I. 1963/1450, 1964/1076 (1963 II, p.2483: 1964 II, p.2380).
(c) 52 & 53 Vict. c. 63.

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 and Importation) General Regulations 1963 relating to the composition of containers of therapeutic substances and of the seals of such containers and the manner of sealing.

They also revoke the requirement that an applicant for an import licence shall be the sole accredited agent of the manufacturer for the import of the substance covered by the licence.