STATUTORY INSTRUMENTS

1977 No. 1051

MEDICINES

The Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Amendment Regulations 1977

Made - - - -	21*st June* 1977
Laid before Parliament	24*th June* 1977
Coming into Operation	15*th July* 1977

The Secretaries of State respectively concerned with health in England and in Wales, the Secretary of State concerned with health and with agriculture in Scotland, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred by sections 18(1) and 36(1) of the Medicines Act 1968(**a**) and now vested in them(**b**) and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by the regulations, hereby make the following regulations:—

Citation, commencent and interpretation

1.—(1) These regulations may be cited as the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Amendment Regulations 1977 and shall come into operation on 15th July 1977.

(2) These regulations shall be read as one with the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971(**c**) as amended(**d**) (hereinafter referred to as "the principal regulations").

Amendments of Schedule 1 to the principal regulations

2.—(1) After paragraph 27 of Part I of Schedule 1 to the principal regulations (particulars required on applications) there shall be inserted the following paragraphs—

> "28. A specimen or mock-up of the labelled container and package in which the medicinal product is to be sold or supplied and a specimen or mock-up of any leaflet relating to the medicinal product which is to be supplied with the product by being enclosed in containers or packages of the product.

(**a**) 1968 c. 67.

(**b**) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of Article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388; 1969 I, p. 1070), and in the case of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36), and section 1(3) of, and paragraph 2(1) (*b*) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

(**c**) S.I. 1971/973 (1971 II, p. 2816).

(**d**) S.I. 1972/1201, 1975/681 (1972 II, p. 3560; 1975 I, p. 2463).

29. Where manufacturing or assembling operations relating to the medicinal product are to be carried out in a place other than in the United Kingdom, documentary evidence that every person taking part in the manufacture or assembly in the course of a business carried on by him is authorised to carry out such operations by the appropriate authority of the country in which such operations are to be carried out.

30. Where an authorisation to sell or supply the medicinal product or to place the product on the market in another country has been obtained, a copy of such authorisation.".

(2) After paragraph 28 of Part II of Schedule 1 to the principal regulations there shall be inserted the following paragraphs—

"29. A specimen or mock-up of the labelled container and package in which the medicinal product is to be sold or supplied and a specimen or mock-up of any leaflet relating to the medicinal product which is to be supplied with the product by being enclosed in containers or packages of the product.

30. Where manufacturing or assembling operations relating to the medicinal product are to be carried out in a place other than in the United Kingdom, documentary evidence that every person taking part in the manufacture or assembly in the course of a business carried on by him is authorised to carry out such operations by the appropriate authority of the country in which such operations are to be carried out.

31. Where an authorisation to sell or supply the medicinal product or to place the product on the market in another country has been obtained, a copy of such authorisation.".

David Ennals,
Secretary of State for Social Services.

13th June 1977.

John Morris,
Secretary of State for Wales.

14th June 1977.

Bruce Millan,
Secretary of State for Scotland.

16th June 1977.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 17th June 1977.

(L.S.)

John Silkin,
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 20th day of June 1977.

(L.S.)

N. Dugdale,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 21st day of June 1977.

(L.S.)

J. A. Young,
Permanent Secretary.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations further amend the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971 by prescribing requirements as to specimens or mock-ups of containers, packages and leaflets and documentary evidence of authorisations obtained in other countries in relation to the manufacture or assembly or the sale, supply or placing on the market of medicinal products to be furnished with applications for product licences. To the extent that the regulations relate to proprietary medicinal products they implement certain Community obligations under two Council Directives Nos. 65/65/EEC and 75/319/EEC.

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