STATUTORY INSTRUMENTS

1983 No. 1726

MEDICINES

The Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Amendment Regulations 1983

Made - - - -	*21st November 1983*
Laid before Parliament	*30th November 1983*
Coming into Operation	*21st December 1983*

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Scotland and in Wales, 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 the powers conferred by section 18(1) of the Medicines Act 1968 and now vested in them(**1**), 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 these regulations in accordance with section 129(6) of the said Act, hereby make the following regulations:—

Title and commencement

1. These regulations may be cited as the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Amendment Regulations 1983 and shall come into operation on 21st December 1983.

Amendment of regulations

2. The Medicines (Applications for Product Licences and Clinical Trail and Animal Test Certificates) Regulations 1971 shall be amended as follows—

(a) in regulation 2(1) (interpretation) after the definition of "proprietary designation" there shall be inserted the following definition—

(**1**) In the case of the Secretaries of State concerned with health in England and Wales by virtue of S.I. 1969/388, in the case of the Secretary of State concerned with agriculture in Wales by virtue of S.I. 1978/272 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).

""proprietary medicinal product" and "ready-made veterinary drug" have the same meanings as in sections 7(7) and 8(4) of the Act(**2**);";

and

(b) for paragraph 26 of Part I of Schedule 1 (particulars required on an application for the grant of a product licence) there shall be substituted the following paragraph—

(a) Any directions, contra-indications and warnings proposed (and in the case of a veterinary drug which is a proprietary medicinal product or a ready-made veterinary drug the reasons for them), and the basic particulars of the information proposed to be included on the container label, on the package label and in any leaflet to be inserted in the package, or in other informative literature, and

(b) in the case of a veterinary drug which is a proprietary medicinal product or a ready-made veterinary drug, particulars of the withdrawal period necessary before an animal which has been treated with the drug is slaughtered for the production of food and before products derived from such an animal are used as food."

Norman Fowler
21st November 1983 — Secretary of State for Social Services

George Younger
1st November 1983 — Secretary of State for Scotland

Nicholas Edwards
2nd November 1983 — Secretary of State for Wales

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 26th October 1983.

L.S.

Michael Jopling
Minister of Agriculture, Fisheries and Food

(**2**) Sections 7(7) and 8(4) were inserted by S.I. 1977/1050 and S.R. (N.I.) No. 170 and amended by S.I. 1983/1724.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this 10th day of November 1983.

L.S.

N. Dugdale
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 10th day of November 1983.

L.S.

W.H. Jack
Permanent Secretary

EXPLANATORY NOTE

These Regulations further amend the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971 which prescribed the manner and form in which an application for the grant of a product licence or the issue of a clinical trial certificate or an animal test certificate is to be made and the information, documents, samples and other material that shall be furnished with each application.

The Regulations amend the 1971 Regulations by prescribing additional particulars which are to be contained in, or accompany, every application for the grant of a product licence in relation to a veterinary drug which is a proprietary medicinal product (as defined in sections 7(7) and 8(4) of the Medicines Act 1968 which sections were inserted in that Act by S.I. 1977/1050 and S.R. (N.I.) 1977 No. 170 and amended by S.I. 1983/1724) or a ready-made veterinary drug (as similarly defined) (Regulation 2).

The Regulations implement in part Council Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products.