STATUTORY INSTRUMENTS

1983 No. 1729

MEDICINES

The Medicines (Labelling) 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 powers conferred by sections 85(1), 85(4) and 91(3) 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 (Labelling) Amendment Regulations 1983 and shall come into operation on 21st December 1983.

Amendment of regulations

2. The Medicines (Labelling) Regulations 1976(**2**) shall be amended as follows—

(a) in regulation 3(1) (interpretation) after the definition of "proprietary designation" there shall be inserted the following definition—

> ""proprietary medicinal product" and "ready-made veterinary drug" have the same meanings as in sections 7(7) and 8(4) of the Act(**3**);";

(b) at the end of paragraph 5 of Schedule 1 (standard particulars required in the labelling of containers and packages) there shall be inserted the words "and in the case of a veterinary drug which is a proprietary medicinal product or a ready-made veterinary drug,

(**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. 1978/2721 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).

(**2**) relevant amending instrument is S.I. 1977/996.

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

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.";

(c) at the beginning of paragraphs 8 and 11 of Schedule 1 there shall be inserted the words "Except in the case of a veterinary drug which is a proprietary medicinal product or a ready-made veterinary drug,";

(d) after paragraph 11 of Schedule 1 (as amended) there shall be inserted the following paragraph—

(A) In the case of a veterinary drug which is a proprietary medicinal product or a ready-made veterinary drug—

(a) the name and address of the holder of the product licence which relates to the drug, and

(b) if different therefrom, the name and address of the person responsible for the composition of the drug.";

and

(e) after paragraph 12 of Schedule 1 there shall be inserted the following paragraph—

"**13.** In the case of a veterinary drug which is a proprietary medicinal product or a ready-made veterinary drug, the species of animal for which the drug is intended and the method and the route of administration.".

Transitional provision

3. These regulations shall not have effect in relation to a medicinal product in respect of which a product licence was granted prior to the coming into operation of these regulations, until 21st December 1985.

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

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 (Labelling) Regulations 1976 which contained requirements relating to the labelling of containers and packages of medicinal products.

The Regulations amend the 1976 Regulations by prescribing additional standard particulars required in the labelling of containers and packages of veterinary drugs which are proprietary medicinal products or ready-made veterinary drugs (as defined in Regulation 2(a)) (Regulation 2(b), (d) and (e)).

The Regulations do not come into operation until 21st December 1985 in relation to a medicinal product in respect of which a product licence was granted prior to 21st December 1983 (Regulation 3).

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.