STATUTORY INSTRUMENTS

1985 No. 2008

MEDICINES

The Medicines (Labelling) and (Leaflets for Veterinary Drugs) (Amendment) Regulations 1985

Made - - - -	18*th December* 1985
Laid before Parliament	20*th December* 1985
Coming into Operation	21*st December* 1985

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(2), 86(1) and 91(3) 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 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) and (Leaflets for Veterinary Drugs) (Amendment) Regulations 1985 and shall come into operation on 21st December 1985.

Amendment of regulations

2.—(1) For paragraph 5 of Schedule 1 to the Medicines (Labelling) Regulations 1976 (standard particulars required in the labelling of containers and packages) (**c**) there shall be substituted the following paragraphs—

"5. Where the medicinal product is for use by being administered to animals, any restrictions on the purposes for which the medicinal product may be used in the provisions of any product licence relating to the medicinal product.

5A. Where the product licence relating to a veterinary drug which is a proprietary medicinal product or a ready-made veterinary drug specifies a withdrawal period before an animal which has been treated with such drug is slaughtered for the production of food and before products derived from such an animal are used as food, the withdrawal period so specified."

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

(**b**) 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).

(**c**) S.I. 1976/1726; relevant amending instrument is S.I. 1983/1729.

(2) For paragraph 9 of the Schedule to the Medicines (Leaflets for Veterinary Drugs) Regulations 1983 (particulars required to be included in leaflets)(**a**) there shall be substituted the following paragraph —

"9. Where the product licence relating to a proprietary veterinary drug or ready-made veterinary drug specifies a withdrawal period before an animal which has been treated with such drug is slaughtered for the production of food and before products derived from such an animal are used as food, the withdrawal period so specified."

Norman Fowler,
Secretary of State for Social Services.

18th December 1985.

George Younger,
Secretary of State for Scotland.

11th December 1985.

Nicholas Edwards
Secretary of State for Wales.

12th December 1985.

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 4th December 1985.

L.S.

Michael Jopling,
Minister of Agriculture,
Fisheries and Food.

(**a**) S.I. 1983/1727.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this 10th day of December 1985.

L.S.

Maurice N. Hayes,
Permanent Secretary.

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 9th day of December 1985.

L.S.

W.H. Jack,
Permanent Secretary.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These regulations further amend the Medicines (Labelling) Regulations 1976 which contained requirements relating to the labelling of containers and packages of medicinal products and amend the Medicines (Leaflets for Veterinary Drugs) Regulations 1983 which prescribe particulars to be contained in leaflets supplied with proprietary veterinary drugs and ready-made veterinary drugs. In each case the Regulations implement in part Council Directive 81/851/EEC (OJ No.L 317, 6.11.81, p.l) on the approximation of the laws of the Member States relating to veterinary medicinal products.

The regulations re-enact in the standard particulars required in the labelling of containers and packages in the 1976 Regulations those particulars concerning restrictions given in a relevant product licence on the purposes for which medicinal products to be administered to animals may be used. The regulations also amend the standard particulars, so that the requirement to show a withdrawal period shall apply only in those cases where such a period is specified in a product licence relating to veterinary drugs which are proprietary medicinal products or ready-made veterinary drugs (regulation 2(1)).

The regulations amend the particulars required to be included in leaflets, in the 1983 Regulations: the particulars now include the withdrawal period, if such a period is specified in a product licence relating to proprietary veterinary drugs and ready-made veterinary drugs (regulation 2(2)).

Printed for Her Majesty's Stationery Office by Albert Gait Ltd. Dd. 0717976

820/G 5106/7646 WO U6 C16 1/86

ISBN 0 11 058008 7