STATUTORY INSTRUMENTS

1983 No. 1727

MEDICINES

The Medicines (Leaflets for Veterinary Drugs) Regulations 1983

Made - - - -	21*st November* 1983
Laid before Parliament	30*th November* 1983
Coming into Operation	21*st 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 86(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 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 (Leaflets for Veterinary Drugs) Regulations 1983 and shall come into operation on 21st December 1983.

Interpretation

2. In these regulations, unless the context otherwise requires—

"the Act" means the Medicines Act 1968;

"medicinal product" has the same meaning as in Section 130(1)(*a*) of the Act;

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

"proprietary veterinary drug" means a veterinary drug which is a proprietary medicinal product.

(**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**) Sections 7(7) and 8(4) were inserted by S.I. 1979/1050 and S.R. (N.I.) 1977 No. 170 and amended by S.I. 1983/1724.

Standard requirements relating to leaflets

3. Subject to the following provisions of these regulations, all leaflets relating to proprietary veterinary drugs or ready-made veterinary drugs which are supplied, or intended to be supplied, with proprietary veterinary drugs or ready-made veterinary drugs shall contain the particulars set out in the Schedule to these regulations.

General provisions

4.—(1) All particulars contained in such a leaflet as is described in regulation 3 above, including the particulars required to be so contained by these regulations, shall be consistent with the provisions of any product licence granted under Part II of the Act in respect of the proprietary veterinary drug or ready-made veterinary drug which relates to such particulars.

(2) All particulars required by these regulations to be contained in such a leaflet shall, except with respect to numerals, be given in the English language.

(3) Except as provided in paragraph (4) below, no such leaflet shall contain any reference to a medicinal product of any description other than the proprietary veterinary drug or ready-made veterinary drug with which that leaflet is supplied or intended to be supplied.

(4) Notwithstanding the provisions of paragraph (3) above, such a leaflet which—

(*a*) contains instructions solely in respect of the use of an apparatus or appliance for the purpose of administration of the proprietary veterinary drug or ready-made veterinary drug to which the leaflet relates, being instructions that are capable of having equal application to other medicinal products having the same pharmaceutical form, or

(*b*) contains the particulars set out in paragraphs 4 to 8 of the Schedule to these regulations, being particulars that would be the same in all respects in relation to other medicinal products of a different description; or

(*c*) contains any reference to a medicinal product other than the proprietary veterinary drug or ready-made veterinary drug to which the leaflet relates in so far as such reference is necessary to explain the contra-indications or precautions or the action to be taken in the event of overdosage of the proprietary veterinary drug or ready-made veterinary drug to which that leaflet relates,

may contain references to such other medicinal products.

(5) The particulars required by these regulations to be contained in such a leaflet shall be clearly separate from the remainder of the contents of the leaflet.

Transitional provision

5. These regulations shall not have effect in relation to a proprietary veterinary drug or a ready-made veterinary drug in respect of which a product licence was granted prior to the coming into operation of these regulations, until 21st December 1985.

Norman Fowler,
Secretary of State for Social Services.

21st November 1983.

George Younger,
Secretary of State for Scotland.

1st November 1983.

Nicholas Edwards,
Secretary of State for Wales.

2nd November 1983.

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.

SCHEDULE

Regulation 3

PARTICULARS REQUIRED TO BE INCLUDED IN LEAFLETS

1. The appropriate non-proprietary name of the proprietary veterinary drug or ready-made veterinary drug (if any) and a proprietary designation.

2. A statement of the appropriate quantitive particulars of the proprietary veterinary drug or ready-made veterinary drug and, where ingredients other than active ingredients are stated, distinguishing between such ingredients as are and such ingredients as are not active ingredients and, where the quantities stated are those from which the drug has been prepared, such quantities being preceded by a statement to that effect, except that where any medicinal product or ingredient is identified by reference to a name, or abbreviation of a name, at the head of a monograph in a specified publication and the quantity of that product or ingredient is stated, the requirements of this paragraph shall be regarded as having been complied with.

3. Where any ingredient has an international non-proprietary name, that name, except that particulars of the international non-proprietary name shall not be required to be given where there is an insignificant difference between the spelling of that international non-proprietary name and such name at the head of a monograph or approved synonym or approved name.

4. The species of animal for which the proprietary veterinary drug or ready-made veterinary drug is intended, the dosage for each species, the method and route of administration and, if necessary, advice on correct administration.

5. Therapeutic indications for the proprietary veterinary drug or ready-made veterinary drug.

6. Contra-indications, warnings and precautions including any contra-indications, warnings and precautions required to be given by the provisions of any product licence relating to the proprietary veterinary drug or ready-made veterinary drug and thereby required to be addressed to the person by whom the product is to be administered.

7. Any special requirements for the handling and storage of the proprietary veterinary drug or ready-made veterinary drug.

8. The name and address of the holder of the product licence which relates to the proprietary veterinary drug or ready-made veterinary drug, and, if different therefrom, the name and address of the person responsible for the composition of the drug.

9. The withdrawal period necessary before an animal which has been treated with the proprietary veterinary drug or ready-made veterinary drug is slaughtered for the production of food and before products derived from such an animal are used as food.

10. In this Schedule the expressions "appropriate non-proprietary name", "appropriate quantitive particulars", "approved name", "international non-proprietary name" and "proprietary designation" have the same meanings as in the Medicines (Labelling) Regulations 1976(a).

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations, made under the Medicines Act 1968, implement in part Council Directive 81/851/EEC (OJ No. L317, 6.11.81, p.1) on the approximation of the laws of the Member States relating to veterinary medicinal products.

The Regulations prescribe particulars to be contained in leaflets supplied with proprietary veterinary drugs and ready-made veterinary drugs (as defined in Regulation 2) (Regulation 3 and Schedule).

Such particulars include the species of animal for which the drug is intended, the dosage for such species, the method and route of administration, contra-indications, warnings and precautions and the withdrawal period necessary before a treated animal is slaughtered for the production of food.

In the case of a proprietary veterinary drug or a ready-made veterinary drug in respect of which a product licence was granted under the Medicines Act 1968 prior to 21st December 1983, the Regulations will not come into operation until 21st December 1985 (Regulation 5).

(a) S.I. 1976/1726; relevant amending instrument is S.I. 1977/996.

SI 1983/1727
ISBN 0-11-037727-3

