

1988 No. 1009

MEDICINES

The Medicines (Labelling of Medicinal Products for  
Incorporation in Animal Feeding Stuffs and of  
Medicated Animal Feeding Stuffs) Regulations 1988

<i>Made</i> - - - -	<i>6th June 1988</i>
<i>Laid before Parliament</i>	<i>16th June 1988</i>
<i>Coming into force</i>	
<i>Regulations 1 and 12</i>	<i>7th July 1988</i>
<i>Remainder</i>	<i>1st November 1988</i>

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), (2) and (4), 86(1), 91(2) and (3) and 129(5) of the Medicines Act 1968(a) and now vested in them(b), and of all other powers enabling them in that behalf, and the Minister of Agriculture, Fisheries and Food, the Secretaries of State concerned with agriculture in Scotland and in Wales and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred by those sections as read with section 90(1) of that Act(c) and now vested in them(d), 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 following Regulations in accordance with section 129(6) of that Act and after consulting and taking into account the advice of the Veterinary Products Committee(e) in accordance with section 129(7) of that Act, hereby make the following Regulations:

**Citation and commencement**

1.—(1) These Regulations may be cited as the Medicines (Labelling of Medicinal Products for Incorporation in Animal Feeding Stuffs and of Medicated Animal Feeding Stuffs) Regulations 1988.

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(a) 1968 c.67; "the appropriate Ministers" referred to in sections 85(1) and 86(1) is defined in section 1 (see also the following footnote); section 91(2) is to be read, as regards England and Wales, with the Magistrates' Courts Act 1980 (c.43), section 32 and S.I. 1984/447, as regards Scotland, with the Criminal Procedure (Scotland) Act 1975 (c.21), section 289B, as substituted by the Criminal Justice Act 1982 (c.48), section 55(2), and S.I. 1984/526, and, as regards Northern Ireland, with S.I. 1984/703 (N.I. 3) and S.R. 1984 No. 253.

(b) In the case of the Secretaries of State concerned with health in England and in 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 the Northern Ireland Constitution Act 1973 (c.36), section 40 and Schedule 5, and the Northern Ireland Act 1974 (c.28), section 1(3) and Schedule 1, paragraph 2(1)(b).

(c) "The Agriculture Ministers" referred to in section 90(1) is defined in section 1(1)(b) (see also the following footnote).

(d) 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 Department of Agriculture for Northern Ireland by virtue of 1973 c.36, section 40 and Schedule 5 and 1974 c.28, section 1(3) and Schedule 1, paragraph 2(1)(b).

(e) A committee established under section 4 of the Medicines Act 1968 by S.I. 1970/1304.

(2) These Regulations shall come into force—

- (a) as respects this regulation and regulation 12 on 7th July 1988, and
- (b) as respects the remainder on 1st November 1988.

### Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

“the Act” means the Medicines Act 1968;

“active ingredient”, in relation to a medicated feeding stuff, means any chemical or other substance specified in a product licence, veterinary written direction or animal test certificate and included in a medicated feeding stuff for a medicinal purpose;

“appropriate non-proprietary name”, in relation to a medicinal product, excepted medicated feeding stuff or ingredient, means—

- (a) where the medicinal product, excepted medicated feeding stuff or ingredient is described in a monograph in a specified publication, any name, or abbreviation of such name, at the head of that monograph or, in the case of the European Pharmacopoeia, an approved synonym or, where such name consists of two or more words, any name derived from a suitable inversion of such words which is permitted by that specified publication, or
- (b) where the medicinal product, excepted medicated feeding stuff or ingredient is not described in a monograph in a specified publication but has an approved name, such approved name, or
- (c) where the medicinal product, excepted medicated feeding stuff or ingredient is not described in a monograph in a specified publication and does not have an approved name, but has an international non-proprietary name, such international non-proprietary name, or
- (d) where the medicinal product, excepted medicated feeding stuff or ingredient is not described in a monograph in a specified publication and does not have an approved name or an international non-proprietary name, the accepted scientific name or any other name descriptive of the true nature of the medicinal product, excepted medicated feeding stuff or ingredient;

“approved name” means the name which appears in the current edition (as defined in section 103(5) of the Act) of the list prepared and published under section 100 of the Act as in force at the time of sale or supply of the medicinal product, excepted medicated feeding stuff or ingredient by the person who has labelled the container of the medicinal product, excepted medicated feeding stuff or ingredient;

“approved synonym” has the same meaning as in section 65(8) of the Act;

“container”, in relation to a medicinal product or medicated feeding stuff, means the bottle, jar, box, packet or other receptacle which contains or is to contain it, not being a capsule, cachet or other article in which the product is or is to be administered, and where any such receptacle is or is to be contained in another such receptacle, includes the former but does not include the latter receptacle;

“data sheet” means a document relating to medicinal products or excepted medicated feeding stuffs of a particular description, which is prepared by or on behalf of the holder of a product licence which is applicable to medicinal products or excepted medicated feeding stuffs of that description and which—

- (a) complies with such requirements as to dimensions and form, as to the particulars to be contained in it, and as to the manner (whether in respect of type, size, colour or disposition of lettering or otherwise) in which any such particulars are to be so contained, as may be prescribed for the purposes of section 96(6) of the Act, and
- (b) does not contain any information relating to medicinal products or excepted medicated feeding stuffs of that description except the particulars so prescribed;

“dosage unit” means that quantity of the medicinal product or excepted medicated feeding stuff which is used as the unit by reference to which the dose of the medicinal product or excepted medicated feeding stuff is measured;

“excepted medicated feeding stuff” means a medicated feeding stuff in respect of which a product licence or animal test certificate has been granted;

“expiry date” means the date after which, or the month and year after the end of which, the medicinal product or excepted medicated feeding stuff should not be used, or the date before which, or the month and year before the beginning of which, the medicinal product or excepted medicated feeding stuff should be used;

“final medicated feeding stuff” means any substance, not being a medicinal product, which is for use wholly or mainly by being fed to one or more animals for a medicinal purpose, or for purposes that include that purpose, without further processing;

“foreign or international compendium of standards” means the national pharmacopoeia or similar compendium of a foreign country published on or before 6th June 1988 or the Specifications for the Quality Control of Pharmaceutical Preparations published by the World Health Organisation on or before 6th June 1988;

“intermediate medicated feeding stuff” means any substance, not being a medicinal product, which is for use wholly or mainly as an ingredient in the preparation of a substance which is to be fed to one or more animals for a medicinal purpose, or for purposes that include that purpose, with or without further processing;

“international non-proprietary name” means a name which has been selected by the World Health Organisation as a recommended international non-proprietary name and in respect of which the Director-General of the World Health Organisation has given notice to that effect in the World Health Organisation Chronicle on or before 6th June 1988;

“medicated feeding stuff” means an intermediate medicated feeding stuff or a final medicated feeding stuff;

“medicinal product” means—

- (a) any medicinal product in respect of which there is a product licence relating to the incorporation of that product in an animal feeding stuff,
- (b) any medicinal product in respect of which there is no product licence but which is intended by virtue of a veterinary written direction or animal test certificate for incorporation in an animal feeding stuff, or
- (c) a substance specified in the Medicines (Control of Substances for Manufacture) Order 1971(a) or the Medicines (Control of Substances for Manufacture) Order 1985(b) which in either case is intended to be incorporated in any animal feeding stuff,

but does not include any herbal remedy to which the provisions of section 12(2) of the Act are applicable;

“package”, in relation to any medicinal products or medicated feeding stuffs, means any box, packet or other article in which one or more containers of the products or feeding stuffs are or are to be enclosed, and, where any such box, packet or other article is or is to be itself enclosed in one or more other boxes, packets or other articles, includes each of the boxes, packets or articles in question;

“person responsible for the composition of the medicinal product or excepted medicated feeding stuff” means a person who in the course of a business carried on by him—

- (a) procures the manufacture of the product or medicated feeding stuff to his order by another person, where the order specifies, or incorporates by reference to some other document, particulars of the composition of the product or medicated feeding stuff ordered, whether those particulars amount to a complete specification or not, or
- (b) manufactures the product or medicated feeding stuff otherwise than in pursuance of an order which fulfils the conditions specified in paragraph (a) above;

“prescription only medicine” means a medicinal product or excepted medicated feeding stuff falling within a description or class for the time being specified for the purposes of section 58 of the Act in an order made under that section;

“proprietary designation” means a word or words used in connection with the sale or supply of medicinal products or excepted medicated feeding stuffs for the purpose

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(a) S.I. 1971/1200.

(b) S.I. 1985/1403.

of indicating that they are the goods of a particular person by virtue of manufacture, selection, certification, dealing or offering for sale or supply;

“quantity” means, where the quantity is not the exact quantity, the quantity which is as near to the exact quantity as is reasonably practicable or which differs from the exact quantity only to such extent as is reasonably necessary in the circumstances having regard to the nature of the medicinal product, excepted medicated feeding stuff or ingredient in question;

“specified publication” has the same meaning as in section 103(1) of the Act;

“standard withdrawal period” in relation to an animal or product of a kind referred to in the first column of Schedule 1 means the withdrawal period set out in the second column of that Schedule opposite that reference;

“veterinary written direction” means a written direction which is given by a veterinary surgeon or a veterinary practitioner and which complies with such requirements as may be specified in regulations under section 40 of the Act(a);

“withdrawal period” means the period from cessation of medication of an animal with a medicated feeding stuff to slaughter of that animal for human consumption or to the taking of products derived from such an animal for human consumption.

(2) Any reference in these Regulations to a numbered regulation or Schedule shall, unless the context otherwise requires, be construed as a reference to the regulation or Schedule bearing that number in these Regulations.

### **Application**

3. Subject to the following provisions of these Regulations, the requirements imposed by these Regulations shall apply to—

- (a) medicinal products, and
- (b) medicated feeding stuffs,

which, in the course of a business carried on by a person, are sold or supplied or are in his possession for the purpose of sale or supply in the United Kingdom.

### **Labelling requirements for containers and packages of medicinal products and excepted medicated feeding stuffs**

4.—(1) Subject to the following provisions of these Regulations, every container and package of a medicinal product or excepted medicated feeding stuff shall be labelled to show the particulars set out in Schedule 2.

(2) Where any container or any package enclosing the container of a medicinal product or excepted medicated feeding stuff is of such a size as to make it impracticable for such container or package to be labelled to show all the particulars required by paragraph (1) above, such container or package shall be labelled to show the particulars set out in paragraphs 1 to 3, 7, 8(a), 10, 11, 14, 15 and 17 of Schedule 2, and a leaflet containing all the particulars required by paragraph (1) above (other than those set out in paragraph 17 of that Schedule) shall be supplied with such container or package and delivered to the purchaser or consignee thereof.

### **Labelling requirements for containers and packages of medicated feeding stuffs other than excepted medicated feeding stuffs**

5.—(1) Subject to the following provisions of these Regulations, every container and package of a medicated feeding stuff (not being an excepted medicated feeding stuff) in which a medicinal product has been incorporated otherwise than in accordance with a veterinary written direction or an animal test certificate shall be labelled to show the particulars set out in Schedule 3.

(2) Subject to the following provisions of these Regulations, every container and package of a medicated feeding stuff (not being an excepted medicated feeding stuff, in which a medicinal product has been incorporated in accordance with a veterinary written direction (but not in accordance with an animal test certificate) shall be labelled to show the particulars set out in paragraphs 1, 2(a), 3 to 7 and 9 of Schedule 3 together with a statement identifying by a reference number the veterinary written direction.

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(a) Section 40 was substituted by the Animal Health and Welfare Act 1984 (c.40), section 13(1).

(3) Where any container or any package enclosing the container of a medicated feeding stuff is of such a size as to make it impracticable for such container or package to be labelled to show all the particulars required by paragraph (1) or (2) above, as the case may be, such container or package shall be labelled to show—

- (a) in the case of a medicated feeding stuff described in paragraph (1) above, the particulars set out in paragraphs 1, 2(a), 3, 10 and 12 of Schedule 3,
- (b) in the case of a medicated feeding stuff described in paragraph (2) above, the particulars set out in paragraphs 1, 2(a) and (3) of Schedule 3 together with a statement identifying by a reference number the veterinary written direction,

and a leaflet containing all the particulars required by paragraph (1) or (2) above, as the case may be, (other than those set out in paragraph 12 of that Schedule) shall be supplied with such container or package and be delivered to the purchaser or consignee thereof.

#### **Medicinal tests on animals**

6.—(1) Subject to paragraphs (2) and (3) below, where—

- (a) a product licence which authorises a medicinal test on animals has been granted in respect of a medicinal product or excepted medicated feeding stuff, or
- (b) an animal test certificate has been granted in respect of a medicinal product or excepted medicated feeding stuff, or
- (c) a medicated feeding stuff (not being an excepted medicated feeding stuff) is for administration in a medicinal test on animals,

every container and package of such medicinal product or medicated feeding stuff shall be labelled with the words “For Animal Test Use Only” and to show the particulars set out in Schedule 4.

(2) Where a product licence has been granted in respect of a medicinal product or excepted medicated feeding stuff and the medicinal product or excepted medicated feeding stuff is to be administered in the same pharmaceutical form as that described in the application for the grant of that product licence and in all respects in accordance with the provisions of that product licence, the words “For Animal Test Use Only” may be omitted.

(3) Where any container or any package enclosing the container of a medicinal product or medicated feeding stuff is of such a size as to make it impracticable for such container or package to be labelled to show all the particulars required by paragraph (1) above, such container or package shall be labelled with the words “For Animal Test Use Only”, subject to paragraph (2) above, and to show the particulars set out in paragraphs 1, 2, 7 and 8 of Schedule 4, and a leaflet containing all the particulars required by paragraph (1) above (other than those set out in paragraph 9 of that Schedule) shall, subject to paragraph (2) above, be supplied with such container or package and be delivered to the purchaser or consignee thereof.

#### **Special labelling requirements relating to medicinal products exempt from product licences and medicated feeding stuffs in which such products have been incorporated**

7.—(1) Where a medicinal product is a product to which the restrictions imposed by section 7 of the Act (product licence) do not apply by virtue of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(a) or the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972(b), every container and any package enclosing the container of such medicinal product shall be labelled to show—

- (a) the particulars set out in paragraphs 1, 3, 9, 10(a) and 15 of Schedule 2, and
- (b) the name and address of the manufacturer of the medicinal product, the name and address of the person responsible for the composition of the medicinal product, if different, and the number of the manufacturer’s licence, if any, preceded by the capital letters “ML”.

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(a) S.I. 1971/1450; the relevant amending instrument is S.I. 1972/1200.

(b) S.I. 1972/1200, to which there are amendments not relevant to these Regulations.

(2) Where a medicinal product to which paragraph (1) above applies has been incorporated into a medicated feeding stuff, every container and any package enclosing the container of such medicated feeding stuff shall be labelled to show the particulars set out or referred to in that paragraph and the standard withdrawal period or any longer period specified in a veterinary written direction relating to the incorporation of the medicinal product in the medicated feeding stuff.

#### **Sale or supply of medicinal products or medicated feeding stuffs not enclosed in a container**

8.—(1) For the purposes of section 85(4) of the Act (sale or supply of medicinal products not enclosed in a container) a person who, in the course of a business carried on by him, sells or supplies a medicinal product or excepted medicated feeding stuff without its being enclosed in a container shall not be taken to contravene regulation 4, 6 or 7 if a leaflet which complies with the requirements of regulation 4, 6 or 7 as appropriate is supplied with the medicinal product or excepted medicated feeding stuff and such leaflet is delivered to the purchaser or consignee thereof together with the medicinal product or excepted medicated feeding stuff.

(2) For the purposes of section 85(4) of the Act (as read with section 90(1) thereof) a person who, in the course of a business carried on by him, sells or supplies a medicated feeding stuff (not being an excepted medicated feeding stuff) without its being enclosed in a container shall not be taken to contravene regulation 5, 6 or 7 if a leaflet which complies with the requirements of regulation 5, 6 or 7 as appropriate is supplied with such medicated feeding stuff and such leaflet is delivered to the purchaser or consignee thereof together with such medicated feeding stuff.

#### **General provisions**

9.—(1) All labelling of containers of medicinal products or medicated feeding stuffs shall be carried out in an indelible manner on, or in such a way that the label is attached to, the body of the container, except that, where the container is a transparent container, such labelling may be carried out inside the body of the container.

(2) All labelling of packages of medicinal products or medicated feeding stuffs shall be carried out in an indelible manner.

(3) Where a medicinal product or excepted medicated feeding stuff contains a single active ingredient and particulars of the appropriate non-proprietary name of such ingredient are required by these Regulations to be shown on the container of the medicinal product or excepted medicated feeding stuff or on the container of the medicated feeding stuff in which the medicinal product or excepted medicated feeding stuff has been incorporated, such appropriate non-proprietary name shall be shown in prominent lettering on the container.

(4) All particulars required by these Regulations to be shown on any labelling of any container or package of a medicinal product or medicated feeding stuff or contained in any leaflet supplied with such medicinal product or medicated feeding stuff shall, except with respect to numerals, be given in the English language, except that—

- (a) where the name of a herbal remedy or ingredient of a herbal remedy at the head of a specified publication is a botanical name, that botanical name may be given, or
- (b) where the name of a medicinal product or excepted medicated feeding stuff is in a language other than English but is the name by which that medicinal product or excepted medicated feeding stuff is usually known in the United Kingdom, that name may be given,

but nothing in this regulation shall prohibit such particulars being given in two or more languages where one of those languages is English.

(5) All particulars referred to in paragraph (4) above shall be clear, legible and readily discernible so as to be easily read by an intending purchaser or user of the medicinal product or medicated feeding stuff under normal conditions of purchase or use.

(6) No labelling of any container or package of a medicinal product or medicated feeding stuff or particulars contained in any leaflet supplied with such medicinal product or medicated feeding stuff shall include any reference, direct or indirect, to the Act or any regulations (including these Regulations) or orders made under the Act or to the

Medicines Commission or to any committee established under section 4 of the Act or to any licence or certificate granted or issued under the Act, unless such reference is required by or made pursuant to the provisions of the Act or such regulations, orders, licence or certificate.

(7) Every container and package of a medicinal product or excepted medicated feeding stuff, not being a container or package of a medicinal product or excepted medicated feeding stuff for administration in a medicinal test on animals, shall be labelled to show the words "For Animal Treatment Only" except that, where such container or package is of so small a size that it is not reasonably practicable to show such words, they may be omitted.

(8) Every leaflet supplied with a medicinal product or excepted medicated feeding stuff, not being a leaflet supplied with a medicinal product or excepted medicated feeding stuff for administration in a medicinal test on animals, or a leaflet which is a data sheet, shall contain the words "For Animal Treatment Only".

### **Removal etc of labels**

10. No person shall intentionally remove, alter or render illegible any label complying with the requirements of these Regulations while such label is affixed to a container or package containing a medicated feeding stuff (not being an excepted medicated feeding stuff) held in the possession of any person for the purpose of sale or supply.

### **Exemptions**

11. Nothing in these Regulations shall require the labelling of—

- (a) any package in the form of a transparent wrapping or cover to a container or package of a medicinal product or medicated feeding stuff, or any package part of which is transparent or open, if the particulars shown on the labelled container or package enclosed in that package are clearly visible, or
- (b) any package in the form of a packing case, crate or other covering used solely for the purposes of transit, transport or delivery of containers or packages of medicinal products or medicated feeding stuffs labelled in accordance with the provisions of these Regulations, or
- (c) any package in the form of a wrapping paper, paper bag or similar covering in which the container or package of a medicinal product or medicated feeding stuff labelled in accordance with the provisions of these Regulations is placed when such medicinal product or medicated feeding stuff is sold by retail or supplied in circumstances corresponding to retail sale, or
- (d) any container or package immediately enclosing the container of a medicinal product or medicated feeding stuff which is for export.

### **Transitional provisions**

12. In any proceedings brought in respect of a contravention alleged to have occurred before 1st November 1988—

- (a) against the Medicines (Labelling of Medicated Animal Feeding Stuff) Regulations 1973(a) or section 85(3) or 86(2) of the Act (as applied by section 90(1) of the Act) in so far as it relates to any contravention of those Regulations, or
- (b) against regulation 14 of the Medicines (Labelling) Regulations 1976(b) or section 85(3) or 86(2) of the Act in so far as it relates to any contravention of that regulation,

the defendant shall not be convicted of an offence unless the prosecution proves additionally that the alleged contravention would have constituted an offence under these Regulations if they had been in force at the time of the alleged contravention.

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(a) S.I. 1973/1530.

(b) S.I. 1976/1726; the relevant amending instruments are S.I. 1977/996, 1978/1140.

## Offences

13. Any person who contravenes the provisions of these Regulations or who contravenes the provisions of section 85(3) or 86(2) of the Act (as applied by section 90(1) of the Act in relation to medicated feeding stuffs other than excepted medicated feeding stuffs) shall be guilty of an offence and—

- (a) shall be liable on summary conviction to a fine not exceeding £2,000, and
- (b) shall be liable on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both.

## Amendment of the Medicines (Labelling) Regulations 1976

14. The Medicines (Labelling) Regulations 1976 shall be amended in accordance with Schedule 5.

## Revocation

15. The Medicines (Labelling of Medicated Animal Feeding Stuff) Regulations 1973 are revoked.

26th May 1988

*John Moore*  
Secretary of State for Social Services

25th May 1988

*Sanderson of Bowden*  
Minister of State, Scottish Office

26th May 1988

*Peter Walker*  
Secretary of State for Wales

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 25th May 1988.

(L.S.)

*John MacGregor*  
Minister of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this 2nd day of June 1988.

(L.S.)

*F. A. Elliot*  
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 6th day of June 1988.

(L.S.)

*David M. Carnson*  
Under Secretary



SCHEDULE 1

Regulation 2(1)

STANDARD WITHDRAWAL PERIODS

<i>Animal or product</i>	<i>Withdrawal period</i>
Fish	A number of days ascertained by measuring once each day following treatment with the medicinal product the temperature of the water in which the fish are kept and cumulating that daily temperature until the cumulative total temperature is at least 200 °C
Pigs	10 days
Poultry	7 days
Rabbits	7 days
Other species of animals	28 days
Eggs (from any species of animal)	7 days
Milk (from any species of animal)	7 days

SCHEDULE 2

Regulations 4(1) and (2),  
7(1) and 8(1)

STANDARD PARTICULARS REQUIRED IN THE LABELLING OF  
CONTAINERS AND PACKAGES OF MEDICINAL PRODUCTS AND  
EXCEPTED MEDICATED FEEDING STUFFS

1. The name of the medicinal product or excepted medicated feeding stuff, being either a proprietary designation or, if no proprietary designation, the appropriate non-proprietary name.

2. Any product licence number as allocated by the licensing authority which relates to the medicinal product or excepted medicated feeding stuff preceded by the letters "PL" in capital letters.

3. A statement, in a conspicuous position, of the quantity (expressed as mg per kg or g per tonne) of each active ingredient in the medicinal product or excepted medicated feeding stuff, identified by its appropriate non-proprietary name.

4. Where under paragraph 1 or 3 above a medicinal product, excepted medicated feeding stuff or ingredient is identified by reference to a name, or abbreviation of such name, at the head of a monograph in a specified publication or in a foreign or international compendium of standards or, in the case of the European Pharmacopoeia, an approved synonym, words or letters identifying the specified publication or compendium and, except where the specified publication or compendium is the current edition, figures giving the edition.

5. Where under paragraph 1 or 3 above a medicinal product, excepted medicated feeding stuff or ingredient is identified by reference to a name, or abbreviation of such name, at the head of a monograph in a specified publication or in a foreign or international compendium of standards or, in the case of the European Pharmacopoeia, an approved synonym, and the international non-proprietary name (if any) of such medicinal product, excepted medicated feeding stuff or ingredient is not the same as such name or approved synonym, that international non-proprietary name followed by the letters "INN" in capital letters, 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 or approved synonym.

6. A description of the pharmaceutical form of the medicinal product or excepted medicated feeding stuff.

7. The purposes for which the medicinal product or excepted medicated feeding stuff is to be used and the directions for use, including—
- (a) the permissible daily level of active ingredient to be administered where this is specified in the product licence which relates to the product or excepted medicated feeding stuff, and
  - (b) the species, and categories within species, of animals to which the medicinal product or excepted medicated feeding stuff is to be administered.
8. In the case of a medicinal product or excepted medicated feeding stuff intended to be incorporated in any animal feeding stuff—
- (a) directions for its incorporation in the animal feeding stuff including the quantity of active ingredient to be present in the final medicated feeding stuff, and
  - (b) a statement that incorporation must be in accordance with the terms of a product licence or animal test certificate relating to the medicinal product or excepted medicated feeding stuff or in accordance with a veterinary written direction.
9. The quantity of the medicinal product or excepted medicated feeding stuff expressed in terms of weight, volume or capacity or number of dosage units.
- 10.(a) Contra-indications, warnings and precautions required to be given by the provisions of any product licence which relates to the medicinal product or excepted medicated feeding stuff and thereby required to be addressed to the user of the medicinal product or excepted medicated feeding stuff.
- (b) Any restrictions on the purposes for which the medicinal product or excepted medicated feeding stuff may be used in the provisions of any product licence which relates to the medicinal product or excepted medicated feeding stuff.
  - (c) Any special requirements for the handling and storage of the medicinal product or excepted medicated feeding stuff.
  - (d) In the case of a medicinal product or excepted medicated feeding stuff intended to be incorporated in any animal feeding stuff, an indication of which of the particulars mentioned in sub-paragraphs (a) to (c) above are to appear on the label of any container or package of the medicated feeding stuff.
- 11.(a) Where a product licence relating to the medicinal product or excepted medicated feeding stuff specifies a withdrawal period, the withdrawal period so specified.
- (b) Where a product licence relating to a prescription only medicine does not specify a withdrawal period, the words "Withdrawal period—see veterinary written direction".
- 12.(a) In the case of a prescription only medicine, the capital letters "POM" within a rectangle within which there shall be no other matter.
- (b) In the case of a medicinal product or excepted medicated feeding stuff which is a veterinary drug specified in Schedule 1, 2 or 4 to the Medicines (Exemptions from Restrictions on the Retail Sale or Supply of Veterinary Drugs) Order 1985(a), the capital letters "PML" within a rectangle within which there shall be no other matter.
  - (c) In the case of a medicinal product or excepted medicated feeding stuff, not being a prescription only medicine, to which any of the restrictions imposed by section 52 of the Act (sale or supply of medicinal products not on general sale list) apply, the capital letter "P" within a rectangle within which there shall be no other matter.
13. The name and address of the holder of any product licence relating to the medicinal product or excepted medicated feeding stuff and, if different, the name and address of the person responsible for the composition of the medicinal product or excepted medicated feeding stuff.
14. Either the expiry date of the medicinal product or excepted medicated feeding stuff, or the date (in terms of month and year) of manufacture of the medicinal product or excepted medicated feeding stuff and the period during which it should be used.
15. The manufacturer's reference number of the batch to which the medicinal product or excepted medicated feeding stuff belongs.
16. Any other statements or particulars required to be stated on the label of any container or package of the medicinal product or excepted medicated feeding stuff, or to be contained in any leaflet supplied with the medicinal product or excepted medicated feeding stuff, by the provisions of any product licence which relates to the medicinal product or excepted medicated feeding stuff.

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(a) S.I. 1985/1823, amended by S.I. 1986/982, 1997, 1987/1123, 1980.

17. In any case where particulars from this Schedule are omitted from a label in accordance with the provisions as to small-sized labels contained in regulation 4(2), a statement that a leaflet of instructions is supplied with the medicinal product or excepted medicated feeding stuff.

### SCHEDULE 3

Regulations 5 and 8(2)

#### STANDARD PARTICULARS REQUIRED IN THE LABELLING OF CONTAINERS AND PACKAGES OF MEDICATED FEEDING STUFFS OTHER THAN EXCEPTED MEDICATED FEEDING STUFFS

1. The name of the medicated feeding stuff, or a description of its nature, and a statement that it is an intermediate medicated feeding stuff or a final medicated feeding stuff.
2. (a) The name of any medicinal product or excepted medicated feeding stuff incorporated in the medicated feeding stuff, being either a proprietary designation or, if no proprietary designation, the appropriate non-proprietary name, and the number of the product licence (if any) authorising incorporation.  
(b) Where any medicinal product or excepted medicated feeding stuff incorporated in the medicated feeding stuff is a prescription only medicine, a statement to that effect.
3. The appropriate non-proprietary name and quantity (expressed as mg per kg or g per tonne) of each active ingredient contained in the medicated feeding stuff.
4. The medicinal purpose for which any medicinal product or excepted medicated feeding stuff has been incorporated in the medicated feeding stuff and the species, and categories within species, of animals to which it is intended the feeding stuff should be fed.
5. Directions for use, including—
  - (a) instructions for the rate at which the medicated feeding stuff should be given to animals, including the permissible daily level of active ingredient to be fed, where this is specified in the product licence relating to the medicinal product or excepted medicated feeding stuff incorporated in the feeding stuff,
  - (b) in the case of an intermediate medicated feeding stuff only, the rate or rates of inclusion with other feeding stuffs and the level of active ingredient to be present in the final medicated feeding stuff.
6. (a) Any warnings or instructions relating to safety, storage or any other matter specified in a product licence relating to any medicinal product or excepted medicated feeding stuff contained in the medicated feeding stuff, which are relevant to the incorporation in feeding stuffs of that medicinal product or excepted medicated feeding stuff.  
(b) In the case of an intermediate medicated feeding stuff only, an indication of which of those warnings or instructions are to appear on the label of any container or package of the final medicated feeding stuff.
7. (a) Where the medicated feeding stuff contains a medicinal product or excepted medicated feeding stuff which has been incorporated in accordance with a product licence, a statement of any withdrawal period specified in that licence.  
(b) Where the medicated feeding stuff contains a prescription only medicine which has been incorporated in accordance with a product licence and that licence does not specify a withdrawal period, the words "Withdrawal period—see veterinary written direction".
8. The name and address of the manufacturer of the medicated feeding stuff or of the person selling or supplying it within the United Kingdom.
9. If the period during which any active ingredient in the medicated feeding stuff remains effective is shorter than the period during which the medicated feeding stuff is recommended by the manufacturer as suitable for use as food for animals—
  - (a) a statement of the date (in terms of month and year) by which that feeding stuff should be consumed if the active ingredient is to be effective, or
  - (b) a statement of the date (in terms of month and year) of manufacture of that feeding stuff and the period during which that feeding stuff should be consumed if the active ingredient is to be effective.

10. The manufacturer's reference number of the batch to which the medicated feeding stuff belongs.

11. Any other statements or particulars required to be stated on the label of any container or package of the medicated feeding stuff, or to be contained in any leaflet supplied with the medicated feeding stuff, by a product licence relating to any medicinal product or excepted medicated feeding stuff contained in the medicated feeding stuff.

12. In any case where particulars from this Schedule are omitted from a label in accordance with the provisions as to small-sized labels contained in regulation 5(3), a statement that a leaflet of instructions is supplied with the medicated feeding stuff.

#### SCHEDULE 4 Regulations 6(1) and (3) and 8

### PARTICULARS REQUIRED IN THE LABELLING OF CONTAINERS AND PACKAGES OF MEDICINAL PRODUCTS OR MEDICATED FEEDING STUFFS FOR MEDICINAL TESTS ON ANIMALS

1. Such designation as will sufficiently identify the animal test.
2. (a) Where more than one medicinal product or excepted medicated feeding stuff is supplied in the course of the animal test, such designation on the container of each medicinal product or excepted medicated feeding stuff as will sufficiently identify each such medicinal product or excepted medicated feeding stuff.  
(b) Where more than one medicinal product or excepted medicated feeding stuff has been incorporated in the medicated feeding stuff which is supplied in the course of the animal test, such designation on the container of the medicated feeding stuff as will sufficiently identify each such medicinal product or excepted medicated feeding stuff.
3. The quantity of the medicinal product or of each active ingredient contained in the medicated feeding stuff expressed in terms of weight, volume or capacity or number of dosage units.
4. The purposes for which the medicinal product or medicated feeding stuff is to be used, the species, and categories within species, of animals to which it is to be administered and the directions for use including dosage and any warning statements.
5. In the case of a medicinal product or intermediate medicated feeding stuff, the directions for incorporation of that medicinal product or intermediate medicated feeding stuff in any animal feeding stuff, and a statement that such incorporation must be in accordance with the terms of a product licence or animal test certificate.
6. Any special requirements for the handling and storage of the medicinal product or medicated feeding stuff.
7. (a) In the case of a medicinal product or excepted medicated feeding stuff, the expiry date.  
(b) In the case of a medicated feeding stuff (not being an excepted medicated feeding stuff) where the period during which any active ingredient in that feeding stuff remains effective is shorter than the period during which the medicated feeding stuff is recommended by the manufacturer as suitable for use as food for animals—
  - (i) a statement of the date (in terms of month and year) by which that feeding stuff should be consumed if the active ingredient is to be effective, or
  - (ii) a statement of the date (in terms of month and year) of manufacture of that feeding stuff and the period during which that feeding stuff should be consumed if the active ingredient is to be effective.
8. Any other statement or particulars required to be stated on the label of any container or package of the medicinal product or medicated feeding stuff, or to be contained in any leaflet supplied with the medicinal product or medicated feeding stuff, by the provisions of an animal test certificate or product licence.
9. In any case where particulars from this Schedule are omitted from a label in accordance with the provisions as to small-sized labels contained in regulation 6(3), a statement that a leaflet of instructions is supplied with the medicinal product or medicated feeding stuff.

## AMENDMENT OF THE MEDICINES (LABELLING) REGULATIONS 1976

1. In regulation 3(1) thereof (interpretation)—
  - (a) there shall be inserted at the end of the definition of “medicinal product” the words “or any medicinal product or excepted medicated feeding stuff to which the Medicines (Labelling of Medicinal Products for Incorporation in Animal Feeding Stuffs and of Medicated Animal Feeding Stuffs) Regulations 1988 apply”;
  - (b) the definitions of “animal feeding stuff”, “complete feeding stuff”, “feed supplement”, “medicated” and “protein concentrate” shall be omitted.
2. Regulation 14 thereof and Schedule 4 thereto (medicinal products for incorporation in animal feeding stuffs or which are medicated animal feeding stuffs in respect of which a product licence or animal test certificate has been granted) shall be omitted.
3. In regulation 18(2)(iv) thereof (exemptions), the words from “, not being” to “are applicable” shall be omitted.
4. In Schedule 3 thereto (particulars required in the labelling of containers and packages of medicinal products for medicinal tests on animals), paragraph 5 shall be omitted.

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations consolidate with amendments the Medicines (Labelling of Medicated Animal Feeding Stuffs) Regulations 1973 and that part of the Medicines (Labelling) Regulations 1976, as amended, ("the 1976 Regulations") which dealt with medicinal products for incorporation in animal feeding stuffs and medicated animal feeding stuffs in respect of which a product licence or an animal test certificate had been granted under the Medicines Act 1968. The 1976 Regulations implemented 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.

These Regulations impose detailed requirements relating to the labelling of containers and packages of such medicinal products and medicated feeding stuffs which are sold or supplied in the United Kingdom in the course of a business or are in the possession of any person for the purpose of sale or supply in the United Kingdom (regulation 3).  
The Regulations—

- (a) prescribe standard labelling requirements in respect of medicinal products and excepted medicated feeding stuffs (regulation 4 and Schedule 2) and other medicated feeding stuffs (regulation 5 and Schedule 3);
- (b) prescribe special labelling requirements in respect of—
  - (i) medicinal products and medicated feeding stuffs for administration in medicinal tests on animals (regulation 6 and Schedule 4);
  - (ii) certain medicinal products exempt from product licences and medicated feeding stuffs in which such products have been incorporated (regulation 7);
- (c) make provision for the sale or supply of medicinal products and medicated feeding stuffs not enclosed in a container, if specified particulars are set out in an accompanying leaflet (regulation 8);
- (d) impose general requirements relating to such matters as the manner of labelling (regulation 9), prohibit the removal of labels in certain circumstances (regulation 10), provide exemptions (regulation 11) and transitional provisions (regulation 12) and create offences (regulation 13).

The principal changes of substance effected by these Regulations are—

- (a) the requirement to specify in certain cases a withdrawal period or standard withdrawal period before an animal treated with a medicated feeding stuff is slaughtered for human consumption and before products derived from such an animal are taken for human consumption (regulations 2(1) and 7(2), Schedule 1, Schedule 2, paragraph 11 and Schedule 3, paragraph 7);
- (b) the increase of the maximum fine which may be imposed on summary conviction for an offence against the Regulations or against certain provisions of the Medicines Act 1968 relating to labelling from £400 to £2,000 (regulation 13(a)).