
STATUTORY INSTRUMENTS

1988 No. 1009

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

Citation and commencement

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

(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⁽¹⁾ or the Medicines (Control of Substances for Manufacture) Order 1985⁽²⁾ 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 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⁽³⁾;

“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.

(1) S.I. 1971/1200.

(2) S.I. 1985/1403.

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

(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.

(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(4) or the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972(5), 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”.

(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.

(4) [S.I. 1971/1450](#); the relevant amending instrument is [S.I. 1972/1200](#).

(5) [S.I. 1972/1200](#), to which there are amendments not relevant to these Regulations.

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(6) 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(7) or section 85(3) or 86(2) of the Act in so far as it relates to any contravention of that regulation,

(6) S.I. 1973/1530.

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

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.

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