STATUTORY INSTRUMENTS

1973 No. 1530

MEDICINES

The Medicines (Labelling of Medicated Animal Feeding Stuffs) Regulations 1973

Made - - -	*29th August* 1973
Laid before Parliament	*18th September* 1973
Coming into Operation	*1st January* 1974

The Minister of Agriculture, Fisheries and Food, the Secretary of State concerned with agriculture in Scotland, and the Secretary of State for Northern Ireland, acting jointly in exercise of powers conferred by sections 85(1) 86(1) and 91(2) and (3) of the Medicines Act 1968(**a**) (as read with section 90(1) of that Act and the provisions of the Medicines (Feeding Stuffs Additives) Order 1973(**b**)) and now vested in them(**c**), and of all other powers enabling them in that behalf, having taken into account the advice of the Veterinary Products Committee established by the Medicines (Veterinary Products Committee) Order 1970(**d**) and after consulting such organisations as appear to them to be representative of interests likely to be substantially affected, hereby make the following regulations:—

Citation, commencement and extent

1. These regulations, which shall be known as the Medicines (Labelling of Medicated Animal Feeding Stuffs) Regulations 1973, shall come into operation on 1st January 1974 and shall extend to the United Kingdom.

Interpretation

2.—(1) In these regulations—

"active ingredient" means any chemical or other substance specified in a product licence or animal test certificate and included in a medicated feeding stuff for a medicinal purpose;

"animal feeding stuff" includes a complete feeding stuff, a feed supplement and a protein concentrate;

"complete feeding stuff" means a substance or a mixture of substances designed for feeding to animals without further mixing with other feeding stuffs;

"feed supplement" means a substance or a mixture of substances designed for further mixing before feeding to animals at an inclusion rate of less than 5% with other animal feeding stuffs;

(a) 1968 c. 67. **(b)** S.I. 1973/1164 (1973 II, p. 3531).
(c) In the case of the Secretary of State for Northern Ireland under the provisions of section 1(1) (a) of the Northern Ireland (Temporary Provisions) Act 1972 (c. 22).
(d) S.I. 1970/1304 (1970 III, p. 4335).

"medicated" when used in relation to an animal feeding stuff, feed supplement or protein concentrate, means having a medicinal product or a substance incorporated for a medicinal purpose, incorporated therein;

"protein concentrate" means a substance or a mixture of substances designed for further mixing before feeding to animals at an inclusion rate of 5% or more with other animal feeding stuffs;

"veterinary prescription" means a written prescription given by a veterinary surgeon or a veterinary practitioner;

and other expressions have the same meaning as in the Medicines Act 1968.

(2) The Interpretation Act 1889(a) shall apply to the interpretation of these Regulations as it applies to the interpretation of an Act of Parliament.

Application

3. The requirements imposed by these regulations shall apply to any medicated animal feeding stuff (not being a substance in respect of which a product licence or an animal test certificate has been granted under the Medicines Act 1968) which in the course of a business is sold or supplied or is in the possession of any person for the purpose of sale or supply.

Particulars which may be required on labels or in leaflets

4. The following particulars shall be shown on any label on any container or package containing any medicated animal feeding stuff to which requirements imposed by these regulations apply or in any leaflet accompanying any such feeding stuff, when so provided by these regulations, viz:—

(*a*) the name of the medicated animal feeding stuff or a description of its nature;

(*b*) the name and address of the manufacturer of the medicated animal feeding stuff or of the person selling or supplying the said feed within the United Kingdom;

(*c*) the manufacturer's reference number of the batch to which the medicated animal feeding stuff belongs;

(*d*) in the case of a medicated feed supplement or medicated protein concentrate sold or supplied otherwise than to a manufacturer of medicated animal feeding stuffs or to a person supplying such a manufacturer, a statement that the medicated animal feeding stuff is a medicated feed supplement or a medicated protein concentrate;

(*e*) the proprietary name of any medicinal product incorporated in the medicated animal feeding stuff together with the appropriate non-proprietary designation or other description by which the active ingredient can readily be identified, and the number of the product licence (if any) authorising incorporation;

(*f*) the common chemical name of any substance (other than a medicinal product) incorporated in the medicated animal feeding stuff for a medicinal purpose and the number of the product licence (if any) authorising such incorporation;

(*g*) the medicinal purpose for which any medicinal product or substance other than a medicinal product has been incorporated in the medicated

(a) 1889 c. 63.

animal feeding stuff and the species, and categories within species, of animals to which it is intended the feeding stuff should be fed;

(*h*) the quantity (in terms of parts by weight or as a proportion of the whole) of each active ingredient contained in the medicated animal feeding stuff;

(*i*) instructions for the rate at which the medicated animal feeding stuff should be given to animals including the permissible daily level of active ingredient to be fed, where this is specified in a relevant product licence; and, in the case of a medicated feed supplement or medicated protein concentrate, the rate or rates of inclusion with other animal feeding stuffs and the level of active ingredient to be present in the complete feed;

(*j*) except in the case of a complete feeding stuff, a statement that the medicated animal feeding stuff must be incorporated in any other animal feeding stuff either in accordance with the terms of a product licence relating to the medicinal product, or to the substance incorporated in the medicated feeding stuff for a medicinal purpose, or in accordance with a veterinary prescription;

(*k*) any instructions relating to safety, storage or any other matter specified in any product licence relating to any medicinal product or substance contained in the medicated animal feeding stuff, which are relevant to the incorporation of that medicinal product or substance in animal feeding stuffs;

(*l*) if the period during which any active ingredient in the medicated animal feeding stuff remains effective is shorter than the period during which the medicated animal feeding stuff is recommended by the manufacturer as suitable for use as food for animals, a statement of the date (in terms of month and year) by which such medicated animal feeding stuff should be consumed if the active ingredient is to be effective;

(*m*) in any case where particulars from this regulation are omitted from a label in accordance with the provisions as to small sized labels contained in regulation 5(4) hereof, a statement that a leaflet of instructions accompanies the medicated animal feeding stuff;

(*n*) any other statement or particulars required to be stated on the labels of any container or package of a medicated animal feeding stuff by a product licence relating to any medicinal product or substance contained in the medicated feeding stuff.

Requirements as to labelling of medicated feeding stuffs

5.—(1) Subject to paragraph (4) of this regulation, any container or package containing a medicated animal feeding stuff in which a medicinal product or substance has been incorporated otherwise than in accordance with a veterinary prescription, directions of the proposed purchaser thereof or an animal test certificate shall be labelled to show the particulars set out in regulation 4 hereof.

(2) Subject to paragraph (4) of this regulation any container or package containing a medicated animal feeding stuff in which a medicinal product or substance has been incorporated in accordance with a veterinary prescription or in accordance with the directions of the proposed purchaser thereof (but not in accordance with an animal test certificate) shall be labelled to show the

particulars set out in sub-paragraphs (*a*), (*h*), (*i*), (*k*) and (*n*) of regulation 4 hereof together with a statement identifying by a reference number the veterinary prescription or the purchaser's order by reference to which the medicated animal feeding stuff has been manufactured.

(3) Subject to paragraph (4) of this regulation, any container or package containing a medicated animal feeding stuff in which a medicinal product or substance has been incorporated in accordance with the terms of an animal test certificate shall be labelled to show the particulars set out in regulation 4 hereof (other than the particulars contained in sub-paragraph (*g*) thereof) but substituting in the case of the particulars required by sub-paragraphs (*e*) and (*f*) the number of the relevant animal test certificate for the licence number and, (if desired), the code number in the relevant animal test certificate in place of the name of the medicinal product or substance.

(4) In any case where any container or package containing a medicated animal feeding stuff is too small to permit a label large enough to carry all the particulars set out in regulation 4 to be shown thereon, such container or package shall be labelled to show the particulars set out in sub-paragraphs (*a*), (*c*), (*e*), (*f*), (*h*), (*i*), (*k*) and (*m*) of regulation 4 hereof, and a leaflet containing all the particulars set out in the said regulation (other than those set out in sub-paragraph (*m*) thereof) shall accompany the container or package and be delivered to the purchaser or consignee thereof.

Requirements as to provision of leaflets

6. Notwithstanding the provisions of section 85(4) of the Medicines Act 1968 (as read with section 90(1) thereof) it shall be lawful for any person to sell or supply a medicated animal feeding stuff without its being enclosed in a container in a leaflet containing the particulars set out in regulation 4 hereof (other than those set out in sub-paragraph (*m*) of that regulation) accompanies the feeding stuff and is delivered to the purchaser or consignee thereof together with the feeding stuff.

Lettering etc. of labels and leaflets

7. Any particulars required by these regulations to be shown on any label on any container or package containing, or in any leaflet accompanying, a medicated animal feeding stuff shall be marked clearly and legibly in letters and figures of a minimum height of 1·5 millimetres on a contrasting ground so as to be readily discernible and easily read, and in such manner as to give prominence to the particulars relating to the rate of incorporation of the medicated animal feeding stuff and to the particulars relating to safety.

Removal of labels

8. No person shall wilfully 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 animal feeding stuff held in the possession of any person for the purpose of sale or supply.

Exemptions

9. Nothing in these regulations shall require the labelling of—

(*a*) any transparent wrapping or cover to a container or package; or

(*b*) any wrapping, packing case, crate or other covering used solely for the purpose of transit, transport or delivery of a container or package labelled in accordance with these regulations; or

(*c*) any wrapping paper or any paper bag (or similar covering) in which a container or package labelled in accordance with these regulations is put when being sold or supplied to the purchaser or other person supplied; or

(*d*) any medicated animal feeding stuff sold or supplied for exportation, provided that the container or package in which such feeding stuff is contained is labelled in accordance with the requirements of the importing country.

Offences

10. Any person who contravenes these regulations, or who contravenes the provisions of sections 85(3) or 86(2) of the Medicines Act 1968 as applied by section 90(1) of that Act shall be guilty of an offence and—

(*a*) shall be liable on summary conviction to a fine not exceeding £400, 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.

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 17th August 1973.

(L.S.)

Joseph Godber,
Minister of Agriculture, Fisheries and Food.

Gordon Campbell,
Secretary of State for Scotland.

29th August 1973.

W. S. I. Whitelaw,
Secretary of State for Northern Ireland.

24th August 1973.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations set out detailed particulars required on labels of containers or packages of medicated animal feeding stuffs (or in specified circumstances, in leaflets accompanying such feeding stuffs) which are sold or supplied in the course of a business or are in the possession of any person for such purposes. Provision is made for the sale or supply of medicated animal feeding stuffs otherwise than in containers provided a leaflet containing specified particulars accompanies such feeding stuffs.

The wilful removal or defacement of a label complying with the requirements of these Regulations from a container or package of medicated animal feeding stuffs held for sale or supply is forbidden, and the penalties laid down in section 91(2) of the Medicines Act 1968 are made applicable to breaches of the Regulations and of sections 85(3) and 86(2) of that Act in their application to animal feeding stuffs.

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