

1977 No. 2168

MEDICINES

**The Medicines (Labelling) Amendment (No. 2)
Regulations 1977**

Made - - - - 20th December 1977

Laid before Parliament 5th January 1978

Coming into Operation 1st February 1978

The Secretaries of State respectively concerned with health in England and in Wales, the Secretary of State concerned with health and with agriculture in Scotland, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred by sections 85(1), 85(4) and 91(2) and (3) of the Medicines Act 1968(a) and now vested in them(b) and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by the following regulations, hereby make the following regulations:—

Citation and interpretation

1. These regulations, which may be cited as the Medicines (Labelling) Amendment (No. 2) Regulations 1977, shall be read as one with the Medicines (Labelling) Regulations 1976(c) as amended(d) (hereinafter referred to as “the principal regulations”) and shall come into operation on 1st February 1978.

Amendment of regulation 14D of the principal regulations

2. Regulation 14D of the principal regulations shall be amended as follows—

- (1) The existing paragraph shall be numbered paragraph “(1)”;
- (2) The following paragraphs shall be inserted after paragraph (1)—
 - “(2) Subject to the following provisions of these regulations, where a medicinal product (not being a dispensed medicinal product) which is a veterinary drug specified in Schedules 1, 2 or 3 to the Medicines

(a) 1968 c. 67.

(b) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of Article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388 (1969 I, p. 1070)), and in the case of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36) and section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

(c) S.I. 1976/1726 (1976 III, p. 4570).

(d) S.I. 1977/996 (1977 II, p. 2813).

(Exemptions from Restrictions on the Retail Sale or Supply of Veterinary Drugs) Order 1977(a) is sold by retail or supplied in circumstances corresponding to retail sale or is offered or exposed for sale by retail, every container and every package immediately enclosing a container of such product—

(a) shall be labelled to show—

- (i) where the veterinary drug is one which is specified in Schedule 1 or 2 to the above order, the letters “PML”;
- (ii) where the veterinary drug is one which is specified in Schedule 3 to the above order, the letters “POM”;

such letters to be in capitals within a rectangle within which there shall be no other matter of any kind,

(b) shall, where the veterinary drug is described in paragraph 6 or 7 of Schedule 6 to these regulations, be labelled to show the words and particulars set out in such paragraph or paragraphs as the case may be,

(c) shall be labelled in accordance with the provisions of regulation 14A of these regulations as if such provisions applied to such containers and packages as they apply to containers and packages of medicinal products on a general sale list.

(3) The requirements of paragraph (2)(a) above shall apply to every package immediately enclosing a container of a veterinary drug which is sold by way of wholesale dealing and which is not on a general sale list.

(4) Where a container or package is required by this regulation to be labelled to show any of the words or particulars contained in paragraph 6 or 7 of the said Schedule 6, such words or particulars shall be within a rectangle within which there shall be no other matter of any kind, except that where words or particulars set out in both of those paragraphs appear on the container or package then they may together be within a rectangle within which there shall be no other matter of any kind.”

Amendment of Regulation 14E of the principal regulations

3. Regulation 14E(1) of the principal regulations shall be amended by the addition of the words “or 14D(2)” after the words “provisions of regulations 14A to 14C”.

David Ennals,

Secretary of State for Social Services.

15th December 1977.

John Morris,

Secretary of State for Wales.

15th December 1977.

Bruce Millan,

Secretary of State for Scotland.

15th December 1977.

(a) S.I. 1977/2167. (1977 III, p. 6141).

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 14th December 1977.

(L.S.)

John Silkin,
Minister of Agriculture, Fisheries
and Food.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this 19th day of December 1977.

(L.S.)

N. Dugdale,
Permanent Secretary.

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 20th day of December 1977.

(L.S.)

J. A. Young,
Permanent Secretary.

EXPLANATORY NOTE

(This Note does not form part of the Regulations.)

These Regulations amend the Medicines (Labelling) Regulations 1976 (as amended) by adding three new paragraphs to regulation 14D, containing labelling requirements for certain veterinary drugs.

There is one other minor consequential amendment.

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