STATUTORY INSTRUMENTS

1985 No. 1558

MEDICINES

The Medicines (Labelling) Amendment Regulations 1985

Made - - - -	*9th October* 1985
Laid before Parliament	*10th October* 1985
Coming into Operation	*31st October* 1985

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Wales and 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), 91(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, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by these regulations pursuant to section 129(6) of that Act, and after consulting and taking into account the advice of the Medicines Commission pursuant to section 129(7) of that Act, hereby make the following regulations:—

Citation, interpretation and commencement

1. These regulations, which may be cited as the Medicines (Labelling) Amendment Regulations 1985, amend the Medicines (Labelling) Regulations 1976(**c**) (hereinafter referred to as "the principal regulations") and shall come into operation on 31st October 1985.

Amendment of Schedule 1 to the principal regulations

2.—(1) At the beginning of paragraph 7 of Schedule 1 to the principal regulations (standard particulars required in the labelling of containers and packages), there shall be inserted the following words—

"Subject to the provisions of paragraph 7A below,".

(2) Immediately after paragraph 7 of Schedule 1 to the principal regulations there shall be added the following paragraph—

(**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), in the case of the Secretary of State concerned with agriculture in Wales by virtue of Article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272) and in the case of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36), and section 1(3) of, and paragraph 2(1)(*b*) of Schedule 1 to the Northern Ireland Act 1974 (c. 28).

(**c**) S.I. 1976/1726, to which there are no amendments relevant to these regulations.

"7A. Where a medicinal product is for use by being administered to one or more human beings, the expiry date in plain language".

Temporary and transitional provision

3. These regulations shall not have effect until 1st January 1990 in relation to a medicinal product in respect of which an application for a product licence under Part II of the Medicines Act 1968 has been granted by the licensing authority provided that such application was received by that authority prior to the coming into operation of these regulations.

Signed by authority of the Secretary of State for Social Services.

R. W. Whitney,
Parliamentary Under-Secretary of State,
Department of Health and Social Security.

2nd October 1985.

Nicholas Edwards,
Secretary of State for Wales.

3rd October 1985.

George Younger,
Secretary of State for Scotland.

7th October 1985.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on the 9th October 1985.

L.S.

Michael Jopling,
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 7th day of October 1985.

L.S.

Maurice N. Hayes,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 7th day of October 1985.

L.S.

W. H. Jack,
Permanent Secretary.

EXPLANATORY NOTE

(*This Note is not part of the Regulations.*)

These regulations make further amendment to the Medicines (Labelling) Regulations 1976 (referred to as the principal regulations) and implement a Community obligation under Council Directive 83/570/EEC (O.J. No. L332, 28.11.83, p.1). Regulation 2 amends Schedule 1 to the principal regulations so as to provide that containers and packages of medicinal products for human use shall be labelled with the expiry date of those products in plain language. Regulation 3 provides a temporary exemption in relation to medicinal products in respect of which an application for a product licence under Part II of the Medicines Act 1968 has been granted by the licensing authority provided that such application was received by that authority prior to the coming into operation of these regulations so that those products need not comply with these regulations until 1st January 1990.

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