

---

 STATUTORY INSTRUMENTS
 

---

1981 No. 1791

## MEDICINES

**The Medicines (Labelling) Amendment Regulations 1981***Made* - - - - 9th December 1981*Laid before Parliament* 22nd December 1981*Coming into Operation* 12th January 1982

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) 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, hereby make the following regulations:—

*Citation and commencement*

1. These regulations may be cited as the Medicines (Labelling) Amendment Regulations 1981 and shall come into operation on 12th January 1982.

*Amendment of the Medicines (Labelling) Regulations 1976*

2.—(1) The Medicines (Labelling) Regulations 1976(c) are amended in accordance with the following paragraphs of this regulation.

(2) To regulation 14A there is added, after paragraph (4), the following paragraph:—

“(5) Without prejudice to the operation of paragraph (1) of this regulation, every container and every package immediately enclosing a container of a medicinal product which is a product referred to in regulation 8 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980(d) which is not presented for sale in the manner described in relation to that product in that regulation and which is not a dispensed medicinal product shall, where the product—

(a) is sold by retail, or

(b) is supplied in circumstances corresponding to retail sale, or

---

(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; relevant amending instruments are S.I. 1977/996 and 1977/2168.

(d) S.I. 1980/1923.

(c) is in the possession of a person for the purpose of such sale or supply,  
or

(d) is sold by way of wholesale dealing,

be labelled to show the capital letter "P" within a rectangle within which there shall be no other matter of any kind."

(3) After regulation 19, there is inserted the following regulation:—

*"Temporary provision for products sold or supplied by retail*

**19A.** Where, by reason of the coming into operation of an order made under section 51 (general sale list), section 57 (exemptions from restrictions on retail sale or supply) or section 58 (prescription only) of the Act, a container or package of a medicinal product would, but for this regulation, be required by regulations 14A, 14B, 14C or 14D of these regulations to be labelled with new or different words or particulars, that container or package may, during a period of six months from the date of coming into operation of that order, be labelled either—

(a) so as to show those new or different words or particulars, or

(b) so as to comply with such of the requirements imposed by regulations 14A, 14B, 14C or 14D of these regulations as were applicable to it immediately before that date."

*Norman Fowler,*  
Secretary of State for Social Services.

30th November 1981.

*Nicholas Edwards,*  
Secretary of State for Wales.

1st December 1981.

*George Younger,*  
Secretary of State for Scotland.

3rd December 1981.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 4th December 1981.

(L.S.)

*Peter Walker,*  
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 9th day of December 1981.

(L.S.)

*N. Dugdale,*  
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 9th day of December 1981.

(L.S.)

*J. A. Young,*  
Permanent Secretary.

## EXPLANATORY NOTE

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

These Regulations make further amendments to the Medicines (Labelling) Regulations 1976. Under those regulations the requirements as to the labelling of medicinal products may vary according to the status of a product for the purposes of Part III of the Medicines Act 1968 (prescription only, pharmacy sale, sale by agricultural merchants, general sale). One amendment provides that where that status is changed by an order made under that Part of that Act, the product may be labelled according to its previous status for a transitional period of six months following the change. Another amendment requires the labelling as pharmacy sale items of larger packs of certain products which, although on a general sale list, may normally be sold, when in those larger packs, only at a registered pharmacy. As prior to 30th January 1981 those packs were not on the general sale list, this amendment provides only that they shall be labelled in the same manner as that required before 30th January 1981.

SI 1981/1791  
ISBN 0-11-017791-6



780110 177915