

1989 No. 1183

MEDICINES

**The Medicines (Data Sheet and Labelling) Amendment
Regulations 1989**

Made - - - - - *7th July 1989*

Laid before Parliament *11th July 1989*

Coming into force

for all purposes except regulation 4 1st August 1989

for the purposes of regulation 4 1st February 1990

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Scotland and in Wales, 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 the powers conferred upon them by sections 85(1), 91(3), 96(6), 129(1) and (5) and 132(1)(a) of the Medicines Act 1968, (b) and now vested in them (c), and of all other powers enabling them in that behalf and after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by the following 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 and commencement

1.—(1) These Regulations may be cited as the Medicines (Data Sheet and Labelling) Amendment Regulations 1989.

(2) Except as provided in regulation 4, these Regulations shall come into force on 1st of August 1989.

Amendment of the Medicines (Data Sheet) Regulations 1972

2. The Medicines (Data Sheet) Regulations 1972(d) shall be amended by —

(a) in paragraph (10) in column 2 of Schedule 2 to those Regulations (product licence numbers, names and addresses);

(i) omitting all the words from “or (d) the name” to the words “Order 1971 are applicable”; and

(a) See section 132(1) for the definition of “prescribed”; by virtue of that section of the Act the expression “the appropriate Ministers” is to be construed in accordance with section 1(2) of that Act. (b) 1968 c.67. (c) 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); 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). (d) S.I. 1972/2076, to which there are no relevant amending instruments.

- (ii) substituting for the words "either (a), (b), (c) or (d)", the words "either (a), (b) or (c)";
- (b) in paragraph (10) in column 2 of Schedule 3 to those Regulations (product licence numbers, names and addresses);
 - (i) omitting all the words from "or (d) the name" to the words "Order 1971 are applicable"; and
 - (ii) substituting for the words "either (a), (b), (c) or (d)", the words "either (a), (b) or (c)".

Amendment of the Medicines (Labelling) Regulations 1976

3. The Medicines (Labelling) Regulations 1976(a) shall be amended by, in Schedule 1 to those Regulations (standard particulars required in the labelling of containers and packages), omitting:-

- (a) in paragraph 8(b) the final ", or";
- (b) paragraph 8(c) (name and address of specified person);
- (c) in paragraph 9 (product licence number) all the words from "or, where the licensing authority" to the words "or the number of the relevant direction"; and
- (d) in paragraph 12 (particulars specified by Licensing Authority) all the words from "or by a direction given" to the end of that paragraph.

Deferred commencement where directions currently in force

4. For the purposes of any case where a direction issued pursuant to article 3 of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(b) is in force on the 31st July 1989 the amendments made by regulations 2 or 3 shall come into force on 1st February 1990.

Signed by authority of the Secretary of State for Health.

6th July 1989 *D. Mellor*
Minister of State,
Department of Health

6th July 1989 *P. Walker*
Secretary of State for Wales

5th July 1989 *M. B. Forsyth*
Parliamentary Under Secretary of State,
Scottish Office

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 7th July 1989.

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 7th day of July 1989.

F. A. Elliot
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 7th day of July 1989.

W. J. Hodges
Permanent Secretary

(a) S.I. 1976/1726; the relevant amending instruments are S.I. 1977/996, 1983/1729 and 1988/1009. (b) S.I. 1971/1450, to which there are no relevant amending instruments.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to the Medicines (Data Sheet) Regulations 1972 and the Medicines (Labelling) Regulations 1976 consequential upon the revocation of article 3 of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971 by the Medicines (Exemption from Licences) (Special and Transitional Cases) Amendment Order 1989 (S.I. 1989/1184) which comes into force on 1st August 1989, the date on which the amendments made by regulations 2 and 3 take effect. However, regulations 1(2) and 4 provide that in the case of a direction issued pursuant to article 3 which is in force on 31st July 1989 the amendments made by regulations 2 and 3 do not take effect until 1st February 1990.