
STATUTORY INSTRUMENTS

1994 No. 104

MEDICINES

**The Medicines (Labelling and Leaflets)
Amendment Regulations 1994**

<i>Made</i>	- - - -	<i>19th January 1994</i>
<i>Laid before Parliament</i>		<i>24th January 1994</i>
<i>Coming into force</i>	- -	<i>14th February 1994</i>

The Secretaries of State respectively concerned with health in England, in Wales and in Scotland and the Department of Health and Social Services for Northern Ireland, acting jointly, in exercise of powers conferred upon them by sections 85(1), 86(1) and 91(3) of the Medicines Act 1968(1) or, as the case may be, those conferred by the said provisions and now vested in them(2), 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(3), hereby make the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Labelling and Leaflets) Amendment Regulations 1994, and shall come into force on 14th February 1994.

(2) In these Regulations, “the Labelling Regulations” means the Medicines (Labelling) Regulations 1976(4) and “the Leaflets Regulations” means the Medicines (Leaflets) Regulations 1977(5).

Amendment of regulation 3(1) of the Labelling Regulations

2. In regulation 3(1) of the Labelling Regulations (interpretation)—

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- (1) 1968 c. 67. The expression “the appropriate Ministers” is defined in section 1(1)(a) and (2) of that Act as amended by S.I.1969/388, Schedule 1.
- (2) 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 Department of Health and Social Services for Northern Ireland 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).
- (3) See section 129(6) of the Medicines Act 1968.
- (4) S.I.1976/1726; relevant amending instruments are S.I.1977/996 and 2168, 1978/41 and 1140, 1983/1729, 1985/1558, 1988/1009, 1992/3273.
- (5) S.I. 1977/1055; the relevant amending instrument is S.I. 1992/3274.

- (a) after the definition of “homoeopathic product”, there shall be inserted the following definition—
- ““homoeopathic product to which Council Directive [92/73/EEC](#)(⁶) applies” means a medicinal product for human use (which may contain a number of principles) prepared from products, substances or compositions called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by any pharmacopoeia used officially in a member State, other than one—
- (i) prepared in accordance with a magistral or officinal formula as defined in Article 1(4) and (5) of the 1965 Directive, or
- (ii) which satisfies the criteria laid down in Article 2(4) of the 1965 Directive;”;
- (b) in the definition of “product to which Chapters II to V of the 1965 Directive apply”(7) for “and Article 1 of Council Directive [89/381/EEC](#)(e)” there shall be substituted “, Article 1 of Council Directive [89/381/EEC](#)(e) and Article 9(1) of Council Directive [92/73/EEC](#)”.

Insertion of regulation 4F into the Labelling Regulations

3. After regulation 4E of the Labelling Regulations, there shall be inserted the following regulation—

“Standard labelling requirements for containers and packages of certain homoeopathic products

4F.—(1) Containers and packages of homoeopathic products to which Council Directive [92/73/EEC](#) applies shall be labelled in clear and legible form to show a reference to their homoeopathic nature, in particular by clear mention of the words “homoeopathic medicinal product”, in addition to any particulars required by any other provision of these regulations.

(2) Where products referred to in paragraph (1) above are placed on the market in accordance with a certificate granted under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(⁸), containers and packages of such products shall be labelled to show the particulars set out in Schedule 9 to these regulations and no other particulars.

(3) Regulations 5, 11, 14A to E, 15 and 16 of these regulations shall not apply in relation to products referred to in paragraph (2) above.”.

Insertion of Schedule 9 into the Labelling Regulations

4. After Schedule 8 to the Labelling Regulations, there shall be inserted the following Schedule—

“SCHEDULE 9

Regulation 4F(2)

STANDARD LABELLING REQUIREMENTS FOR CONTAINERS
AND PACKAGES OF HOMOEOPATHIC PRODUCTS MARKETED

(6) OJ No. L297, 13.10.92, p. 8.

(7) Definition inserted by regulation 2(4) of S.I. [1992/3273](#).

(8) S.I. [1994/105](#).

UNDER A CERTIFICATE GRANTED UNDER THE MEDICINES
(HOMOEOPATHIC MEDICINAL PRODUCTS FOR HUMAN USE) REGULATIONS 1994

1. The scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used in relation to the homoeopathic manufacturing procedure described therein for that stock or stocks.
2. The name and address of the holder of the certificate of registration and, where different, the name and address of the manufacturer.
3. The method of administration and, if necessary, route.
4. The expiry date of the product in clear terms, stating the month and year.
5. The pharmaceutical form.
6. The contents of the sales presentation.
7. Any special storage precautions.
8. Any special warning necessary for the product concerned.
9. The manufacturer's batch number.
10. The registration number allocated by the licensing authority preceded by the letters "HR" in capital letters.
11. The words "homoeopathic medicinal product without approved therapeutic indications".
12. A warning advising the user to consult a doctor if the symptoms persist during the use of the product."

Amendment of regulation 2(1) of the Leaflets Regulations

5.—(1) Regulation 2(1) of the Leaflets Regulations (interpretation) shall be amended in accordance with the following paragraphs of this regulation.

(2) After the definition of "the Act" there shall be inserted the following definition—

"certificate of registration" means a certificate granted under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994;"(9).

(3) After the definition of "generator" there shall be inserted the following definitions—

"homoeopathic medicinal product" means a medicinal product (which may contain a number of principles) prepared from products, substances or compositions called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by any pharmacopoeia used officially in a member State;

"homoeopathic product to which Council Directive 92/73/EEC(10) applies" means a homoeopathic medicinal product for human use other than one—

- (i) prepared in accordance with a magistral or officinal formula as defined in Article 1(4) and (5) of the 1965 Directive, or
- (ii) which satisfies the criteria laid down in Article 2(4) of the 1965 Directive;"

(4) In the definition of "product to which Chapters II to V of the 1965 Directive apply"(11) for "and Article 1 of Council Directive 89/381/EEC(e)" there shall be substituted "Article 1 of Council Directive 89/381/EEC(e) and Article 9(1) of Council Directive 92/73/EEC".

(9) S.I. 1994/105.

(10) OJ No. L297, 13.10.92, p. 8.

(11) Definition inserted by regulation 2(2) of S.I. 1992/3274.

(5) In the definition of “proprietary medicinal product”, for “but does not include a homoeopathic medicinal product or” there shall be substituted “including a homoeopathic product to which Council Directive 92/73/EEC applies, but does not include a”.

Amendment of regulation 3 of the Leaflets Regulations

6. In paragraph (1) of regulation 3 of the Leaflets Regulations (standard requirements relating to leaflets), after “relevant medicinal products” there shall be inserted “or homoeopathic products to which Council Directive 92/73/EEC applies”.

Insertion of regulation 3B into the Leaflets Regulations

7. After regulation 3A of the Leaflets Regulations, there shall be inserted the following regulation

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“Standard requirements relating to leaflets for homoeopathic products

3B. Subject to the following provisions of these regulations, any leaflet which is enclosed in or supplied with the packaging of a proprietary medicinal product which is a homoeopathic product to which Council Directive 92/73/EEC applies and which is placed on the market in the United Kingdom in accordance with a certificate of registration, shall, in addition to clear mention of the words “homoeopathic medicinal product”, contain the particulars set out in Schedule 3 to these regulations and no other particulars.”.

Amendment of regulation 4 of the Leaflets Regulations

8. In paragraph (1) of regulation 4 of the Leaflets Regulations (general provisions) after the words “Part II of the Act” there shall be inserted “or any certificate of registration”.

Amendment of regulation 5 of the Leaflets Regulations

9. In regulation 5 of the Leaflets Regulations (approval of contents of leaflets)—
- (a) in paragraph (1), after “product licence” there shall be inserted “or of a certificate of registration”;
 - (b) in paragraph (2), after the words “product licence” there shall be inserted “or of a certificate of registration” and after “holder of the licence” there shall be inserted “or certificate”.

Insertion of Schedule 3 into the Leaflets Regulations

10. After Schedule 2 to the Leaflets Regulations, there shall be inserted the following Schedule—

“SCHEDULE 3

Regulation 3B

PARTICULARS REQUIRED TO BE INCLUDED IN
LEAFLETS RELATING TO HOMOEOPATHIC PRODUCTS
MARKETED UNDER A CERTIFICATE OF REGISTRATION

1. The scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used in relation to the homoeopathic manufacturing procedure described therein for that stock or stocks.
2. The name and address of the holder of the certificate of registration and, where different, the name and address of the manufacturer.
3. The method of administration and, if necessary, route.

4. The expiry date of the product in clear terms, stating the month and year.
5. The pharmaceutical form.
6. The contents of the sales presentation.
7. Any special storage precautions.
8. Any special warning necessary for the product concerned.
9. The manufacturer's batch number.
10. The registration number allocated by the licensing authority preceded by the letters "HR" in capital letters.
11. The words "homoeopathic medicinal product without approved therapeutic indications".
12. A warning advising the user to consult a doctor if the symptoms persist during the use of the product."

Signed by authority of the Secretary of State for Health

16th December 1993

Tom Sackville
Parliamentary Under-Secretary of State
Department of Health

19th January 1994

John Redwood
Secretary of State for Wales

16th December 1993

Fraser of Carmyllie
Minister of State The Scottish Office

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 17th December 1993.

F. A. Elliott
Permanent Secretary

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Medicines (Labelling) Regulations 1976 (“the Labelling Regulations”) and the Medicines (Leaflets) Regulations 1977 (“the Leaflets Regulations”) by implementing in part Council Directive [92/73/EEC](#) (OJNo. L297, 13.10.1992, p. 8) (“the Directive”) which widens the scope of Directives [65/65/EEC](#) (OJ No.22, 9.2.1965, p. 369/65) and [75/319/EEC](#) (OJ No. L147, 9.6.1975, p. 13) on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homoeopathic medicinal products.

Regulations 2 to 4 amend the Labelling Regulations. Regulation 2 inserts a definition of “homoeopathic product to which Council Directive [92/73/EEC](#) applies” into regulation 3(1) of the Labelling Regulations (Articles 1(1) and 2(1) of the Directive) and amends the definition of “product to which Chapters II to V of the 1965 Directive apply”.

Regulations 3 and 4 insert a new regulation, 4F and a new Schedule, Schedule 9, which impose standard labelling requirements in respect of homoeopathic products to which Council Directive [92/73/EEC](#) apply (Article 2(2) of the Directive) and (Schedule 9) those of them which are marketed in accordance with a certificate of registration under the [Medicines \(Homoeopathic Medicinal Products for Human Use\) Regulations 1994 \(S. I. 1994/105\)](#) (Article 7(2) of the Directive). New regulation 4F(3) disapplies specified provisions of the Labelling Regulations from the latter.

Regulations 5 to 10 amend the Leaflets Regulations. Regulation 5 inserts definitions of “certificate of registration”, “homoeopathic medicinal product” and “homoeopathic product to which Council Directive [92/73/EEC](#) applies” into regulation 2(1) of those Regulations (Articles 1(1) and 2(1) of the Directive) and makes consequential amendments to other definitions.

Regulations 7 and 10 insert a new regulation, 3B, and a new Schedule, Schedule 3, which set out the particulars required in leaflets relating to homoeopathic medicinal products which are marketed under a certificate of registration under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 (Article 7(2) of the Directive). Regulations 6, 8 and 9 contain consequential amendments.

Other parts of the Directive are implemented by the [Medicines \(Homoeopathic Medicinal Products for Human Use\) Regulations 1994 \(S. I. 1994/105\)](#), the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1994 (S. I.1994/103) and the medicines Act 1968 (Amendment) Regulations 1994 (S. I.1994/101).