

*This Statutory Instrument has been made in consequence of a defect in S.I.1994/101 and is being issued free of charge to all known recipients of that Statutory Instrument.*

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## STATUTORY INSTRUMENTS

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# 1994 No. 276

## MEDICINES

### The Medicines Act 1968 (Amendment) (No. 2) Regulations 1994

<i>Made</i>	- - - -	<i>9th February 1994</i>
<i>Laid before Parliament</i>		<i>10th February 1994</i>
<i>Coming into force</i>	- -	<i>13th February 1994</i>

The Secretary of State for Health and the Minister for Agriculture, Fisheries and Food, acting jointly in exercise of the powers conferred on them by section 2(2) of the European Communities Act 1972<sup>(1)</sup>, being designated for the purposes of that section in relation to medicinal products<sup>(2)</sup>, hereby make the following Regulations:

#### **Citation, commencement and interpretation**

1.—(1) These Regulations may be cited as the Medicines Act 1968 (Amendment) (No. 2) Regulations 1994 and shall come into force on 13th February 1994.

(2) In these Regulations “the Act” means the Medicines Act 1968<sup>(3)</sup> and a reference to a numbered section in these Regulations is a reference to the section of the Act which bears that number.

#### **Revocation**

2. There are hereby revoked the Medicines Act 1968 (Amendment) Regulations 1994<sup>(4)</sup>.

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(1) 1972 c. 68.  
(2) S.I. 1972/1811.  
(3) 1968 c. 67.  
(4) S.I. 1994/101.

### **Section 7 of the Act — dealings with medicinal products**

3.—(1) Section 7(5) (general provisions as to dealing with medicinal products) is amended as follows.

(2) After subsection (2), there is inserted—

“(2A) The restrictions imposed by subsection (2) of this section shall not apply where the medicinal product concerned is a homoeopathic medicinal product in respect of which a certificate of registration has been granted.

(2B) In relation to a homoeopathic medicinal product to which the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(6) apply but in respect of which no certificate of registration has been granted, the references in subsection (2) of this section to the activities of sale or supply and of procuring the sale or supply respectively shall be taken to include references to any activity which amounts to placing such a product on the market within the meaning of Council Directive 92/73/EEC(7) of 22 September 1992.”.

(3) In subsection (6A)—

- (a) at the end of paragraph (a) there is inserted “or”; and
- (b) paragraph (c) and “, or” immediately preceding it are omitted.

(4) In subsection (7), before the definition of “proprietary medicinal product” there is inserted—

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

“homoeopathic medicinal product” means any 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;”.

### **Section 8 of the Act — manufacture and wholesale dealing**

4.—(1) Section 8(8) (provisions as to manufacture and wholesale dealing) is amended as follows.

(2) In subsection (4)—

- (a) at the end of paragraph (a) there is inserted “or”; and
- (b) paragraph (c) and “, or” immediately preceding it are omitted.

(3) In subsection (6), before “proprietary medicinal product” there is inserted “homoeopathic medicinal product,”.

### **Section 24 of the Act — duration and renewal of licence**

5. In section 24(9) (duration and renewal of licence)—

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- (5) Subsection (5) of section 7 was amended by regulation 2(2) of the Medicines (Medicines Act 1968 Amendment) Regulations 1977 (S.I. 1977/1050) and regulation 3 of (N.I.) S.R. 1977 No. 170, regulation 2(2) of S.I. 1983/1724 and regulation 2 of S.I. 1992/604 (which also inserted subsections (6A) and (6B)).
  - (6) S.I. 1994/105.
  - (7) OJ No. L 297, 13.10.92, p. 8.
  - (8) Subsections (3) and (4) of section 8 were amended by regulation 3(2) of S.I. 1977/1050 and regulation 4 of (N.I.) S.R. 1977 No. 170, regulation 3 of S.I. 1983/1724, regulation 3(2) and (3) of S.I. 1992/604 (which also inserted subsections (5) and (6)) and regulation 2 of S.I. 1993/834 (which also inserted subsections (3A), (3B), (3C), (7) and (8)).
  - (9) Section 24 was amended by regulation 4(4) of S.I. 1977/1050 and regulation 5(4) of (N.I.) S.R. 1977 No. 150, and applied by regulation 2 of, and the Schedule to, the Medicines Act 1968 (Application to Radiopharmaceutical-associated Products) Regulations 1992 See also the Medicines Act (Application to Radiopharmaceutical-associated Products) Regulations 1992 (S.I. 1992/605).

- (a) in subsection (1A) after “obligation” there is inserted “(other than an obligation under the 1992 Directive)”;
- (b) in subsection (3)(c) after “this Act” there is inserted “and any Community obligation under the 1965 Directive or the 1992 Directive”; and
- (c) after subsection (6) there is inserted—
  - “(7) In this section “the 1992 Directive” means Council Directive [92/27/EEC](#)(10) of 31st March 1992 on the labelling of medicinal products for human use and on package leaflets.”.

### **Section 28 of the Act — suspension etc. of the licence**

- 6.—(1) Section 28(11) (general power to suspend, revoke or vary licences) is amended as follows.
- (2) In subsection (3)—
    - (a) at the beginning there is inserted “Subject to subsection (3A) of this section”; and
    - (b) in paragraph (j) after “relates” there is inserted “(other than products to which Chapters II to V of the 1965 Directive apply)”.
  - (3) After subsection (3) there is inserted—
    - “(3A) Where a product licence relates to a product to which Chapters II to V of the 1965 Directive apply, the power conferred by this section to suspend a licence shall be exercisable in relation to the licence on the ground that—
      - (a) any of the provisions contained in regulations made under section 85 (labelling and marking of containers and packages) or 86 (leaflets) of this Act, or
      - (b) section 86(4),has to a material extent been contravened in relation to the product by the holder of the licence or by a person procured by him to manufacture or assemble the product.”.
  - (4) The amendments made by this regulation have effect only in relation to licences granted or renewed after the coming into force of these Regulations.

### **Section 86 of the Act—leaflets**

- 7.—(1) After section 86(3) (leaflets), there is inserted—
  - “(4) No person shall, in the course of a business carried on by him, supply a product to which Chapters II to V of the 1965 Directive apply, unless—
    - (a) a leaflet enclosed in, or supplied with, the container or package of the product, or
    - (b) the container or package itself,contains the particulars which a leaflet relating to the product is required by regulations under subsection (1) of this section to contain, and does so in the manner required by such regulations.”.
- (2) The amendment made by this regulation has effect only in relation to products in respect of which product licences (as defined in section 7 of the Act) have been granted or renewed after the coming into force of these Regulations.

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(10) OJ No. L113,30.4.92, p.8.

(11) Section 28 was amended by regulation 2(2) of the Medicines (Medicines Act 1968 Amendment) Regulations 1975 (S.I. [1975/1169](#)), S.R. & (N.I.) [1975/197](#), regulation 4(5) of S.I. [1977/1050](#), regulation 5(5) of (N.I.) S.R. [1977 No.170](#) and by paragraph 3(2) of Schedule 1 to the Anamal Health and Welfare Act [1984 \(c. 40\)](#). See also the Medicines Act (Application to Radiopharmaceutical-associated Products) Regulations 1992 (S.I. [1992/605](#)).

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**Section 91 of the Act — penalties**

8. In section 91(1)(12) (offences under Part V etc.), after “section 86(3)”, there is inserted “or (4)”.

**Section 132 of the Act — interpretation**

9. In section 132(1)(13) (general interpretation), in the definition of “the 1965 Directive”, for “and 89/381/EEC(h);” there is substituted “, 89/381/EEC(h) and Article 9(1) of Council Directive 92/73/EEC;”(14).

Signed by authority of the Secretary of State for Health

*Tom Sackville*  
Parliamentary Under Secretary of State,  
Department of Health

9th February 1994

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food was hereunto affixed on

L.S.  
9th February 1994.

*Gillian Shephard*

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(12) Section 91(1) was amended by section 32(2) of the Magistrates' Courts Act 1980 (c. 43). See also the Criminal Penalties etc. (Increase) Order 1984 (S.I. 1984/447) and the Medicines Act (Application to Radiopharmaceutical-associated Products) Regulations 1992 (S.I. 1992/605).

(13) The definition of “the 1965 Directive” was inserted into section 132(1) by regulation 3 of S.I. 1992/3271.

(14) OJ No. L 297, 13.10.92, p. 8.

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations further amend the Medicines Act 1968 (“the Act”) to implement in part Council Directive [92/73/EEC](#) (“the Homoeopathic Directive”) (OJ L 297, 13.10.92, p. 8) which widens the scope of Directives [65/65/EEC](#) (OJ No. 22, 9.2.1965, p. 369/65) and [75/319/EEC](#) (OJ No. L 147, 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 and Council Directive [92/27/EEC](#) (OJ No. L113, 30.4.92, p. 8) (“the Labelling Directive”) which concerns the labelling of, and leaflets to be provided with, medicinal products.

Regulation 2 revokes the Medicines Act 1968 (Amendment) Regulations 1994 (S.I. [1994/101](#)), regulations 2(3), 3(2) and 6(1) of which were defective. These Regulations replace those; the opportunity has been taken (regulation 7(2)) to clarify the application of regulation 7(1).

Regulation 3 amends section 7 of the Act by adding two new subsections, (2A) which provides that as regards a product in respect of which a certificate of registration has been granted, no requirement arises under section 7, and (2B) which expands the activities caught by section 7(2) to include the placing on the market of a product without such a certificate (see Article 7 of the Homoeopathic Directive). Definitions of the terms “certificate of registration” and “homoeopathic medicinal product” have also been inserted.

Regulation 4 amends section 8 of the Act by removing the exemption from the requirement to obtain a wholesale dealer’s licence for homoeopathic medicinal products for human use which have been imported but not consigned from a member State of the European Community (Article 3 of the Homoeopathic Directive).

Regulation 5 amends section 24 of the Act so as to ensure that the requirements of the Labelling Directive are properly taken into account when an application for renewal of a licence under Part II of the Act is considered (Article 10(2) of the Labelling Directive).

Regulation 6 amends section 28 of the Act by providing for the suspension of a product licence for a medicinal product to which Chapters II to V of the 1965 Directive apply where there is a material contravention of section 86(4) of the Act or of regulations made under the Act concerning leaflets and labelling (Article 11 of the Labelling Directive).

Regulation 7 inserts a new subsection (4) in section 86 of the Act to require, in accordance with Article 6 of the Labelling Directive, that no medicinal product to which Chapters II to V of the 1965 Directive apply is to be supplied unless a leaflet containing specified information is enclosed in, or supplied with, the package, or the package itself carries that information.

Regulation 8 amends section 91 of the Act; the amendments have effect only to provide that contravention of section 86(4) is an offence.

Regulation 9 makes a consequential amendment to the definition of the 1965 Directive in section 132(1) of the Act.

Other parts of the Homoeopathic Directive are implemented by the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 (S.I. [1994/105](#)), the Medicines (Labelling and Leaflets) Amendment Regulations 1994 (S.I. [1994/104](#)) and the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1994 (S.I. [1994/103](#)).

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Other parts of the Labelling Directive are implemented by the Medicines (Labelling) Amendment Regulations 1992 (S.I. [1992/3273](#)) and the Medicines (Leaflets) Amendment Regulations 1992 (S.I. [1992/3274](#)).