STATUTORY INSTRUMENTS

1994 No. 103

MEDICINES

The Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1994

Made - - - -	*23rd December 1993*
Laid before Parliament	*24th January 1994*
Coming into force - -	*14th February 1994*

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 upon them by sections 47(1) and 129(5) 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 (Standard Provisions for Licences and Certificates) Amendment Regulations 1994, and shall come into force on 14th February 1994.

(2) In these Regulations, "the principal Regulations" means the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**4**).

Amendment of regulation 2 of the principal Regulations

2. In regulation 2 of the principal Regulations (interpretation), in paragraph (1)—

(a) after the definition of "blood product" there shall be inserted the following definition—

(**1**) 1968 c. 67.The expression "the Ministers" is defined in section 1(1) 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 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).
(**3**) See section 129(6) of the Medicines Act 1968 (c. 67).
(**4**) S.I.1971/972; relevant amending instruments are S.I.1972/1226, 1974/1523, 1977/1039 and 1053, 1983/1730, 1992/2846, 1993/833.

""certificate of registration" means a certificate granted under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994;"(**5**);

(b) in the definition of "product to which Chapters II to V of the 1965 Directive apply"(**6**) for "and Article 1 of Council Directive 89/381/EEC(**6**)" there shall be substituted ", Article 1 of Council Directive 89/381/EEC(**6**) and Article 9(1) of Council Directive 92/73/EEC"(**7**).

Amendment of Schedule 2 to the principal Regulations

3.—(1) Schedule 2 to the principal Regulations (standard provisions for manufacturer's licences and manufacturer's licences of right) shall be amended in accordance with the following paragraph.

(2) In paragraph 16—

(a) after paragraph (a) of sub-paragraph (3) there shall be inserted the following paragraph:

"(aa) where there is in relation to the product which has been manufactured or assembled, a certificate of registration, to ensure that each batch of the product has been manufactured or assembled and checked in compliance with that certificate and the provisions of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**8**);";

(b) in paragraph (b) of sub-paragraph (3), after "(a)" there shall be inserted "or (as the case may be) (aa)";

(c) in sub-paragraph (5) the words "or to medicinal products that are homoeopathic products" shall be omitted.

Amendment of Schedule 3 to the principal Regulations

4.—(1) Schedule 3 to the principal Regulations (standard provisions for wholesale dealer's licences including wholesale dealer's licences of right) shall be amended in accordance with the following paragraphs.

(2) In paragraph (6), in sub-paragraph (1) after the words "product licence" in both places in which they appear there shall be inserted "or certificate of registration".

(3) In paragraph 8—

(a) at the end of paragraph (a) of sub-paragraph (3) there shall be inserted "or";

(b) after paragraph (a) of sub-paragraph (3) there shall be inserted the following paragraph:

"(aa) where there is in relation to the imported proprietary product, a certificate of registration, to ensure that each batch of product has been tested in accordance with the manufacturing and control file submitted with the application for that certificate;";

(c) in paragraph (b) of sub-paragraph (3), after "(a)" there shall be inserted "or (as the case may be) (aa)".

(**5**) S.I. 1994/105.
(**6**) Definition inserted by regulation 2 of S.I. 1993/833.
(**6**) Definition inserted by regulation 2 of S.I. 1993/833.
(**6**) Definition inserted by regulation 2 of S.I. 1993/833.
(**7**) OJ No. L297, 13.10.92, p. 8.
(**8**) S.I. 1994/105.

Signed by authority of the Secretary of State for Health

Tom Sackville
Parliamentary Under-Secretary of State
16th December 1993 Department of Health

John Redwood
23rd December 1993 Secretary of State for Wales

Fraser of Caimyllie
16th December 1993 Minister of State The Scottish Office

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 20th December 1993.

L.S.

Gillian Shephard
Minister of Agriculture, Fisheries and Food

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

L.S.

F. A. Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 20th December 1993.

L.S.

W. J. Hodges
Permanent Secretary

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 ("the principal 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). The latter two Directives relate to the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products; the Directive lays down additional provisions on homoeopathic medicinal products.

Regulation 2 amends the definition of "product to which Chapters II to V of the 1965 Directive apply" and inserts a definition of "certificate of registration".

Regulation 3 implements Article 3 of the Directive by amending Schedule 2 to the principal Regulations to require the holder of a manufacturer's licence relating to homoeopathic medicinal products for human use to have a qualified person available to carry out the functions specified in paragraph 16(3) of Schedule 2, including, where appropriate, that of ensuring compliance in specified respects with the certificate of registration and the provisions of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994.

Regulation 4 amends Schedule 3 to the principal Regulations by making similar provision in respect of wholesale dealer's licences which relate to products imported otherwise than from member States of the European Community and also so as to provide that wholesale dealers may deal only in products which have a certificate of registration, subject to certain exceptions.

Other parts of the 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 Act 1968 (Amendment) Regulations 1994 (S. I.1994/101).