STATUTORY INSTRUMENTS

1993 No. 833

MEDICINES

The Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1993

Made - - - -	*24th March 1993*
Laid before Parliament	*24th March 1993*
Coming into force - -	*14th April 1993*

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 section 47(1) 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.—(2) These Regulations may be cited as the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1993, and shall come into force on 14th April 1993.

(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 paragraph (1) of regulation 2 of the principal Regulations (interpretation), after the definition of "parenteral administration" there shall be inserted the following—

(**1**) 1968 c. 67. The expression "the Ministers", used in section 47(1), is defined in section 1(1) of that Act as amended.

(**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.

(**4**) S.I. 1971/972; the relevant amending instruments are S.I. 1972/1226, 1974/1523, 1977/675, 1977/1039, 1977/1053, 1983/1730, 1992/2846, 1992/3272.

""product to which Chapters II to V of the 1965 Directive apply" means a medicinal product to which, in accordance with Article 2 of Council Directive 65/65/EEC as amended(**5**), Article 34 of Council Directive 75/319/EEC(**6**), Article 1 of Council Directive 89/342/EEC(**7**), Article 1 of Council Directive 89/343/EEC(**8**) and Article 1 of Council Directive 89/381/EEC(**9**), Chapters II to V of Council Directive 65/65/EEC apply;".

Amendment of Schedule 3 to the principal Regulations

3.—(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 of this regulation.

(2) After paragraph 4 there shall be inserted the following paragraphs—

"**4A.** Where the licence relates to products to which Chapters II to V of the 1965 Directive apply, the licence holder shall institute an emergency plan which ensures effective implementation of any recall from the market which is either—

(a) ordered by the licensing authority or the competent authority of a member State other than the United Kingdom; or

(b) carried out in co-operation with the manufacturer or the holder of the product licence or of the marketing authorisation granted by a the competent authority of a member State other than the United Kingdom in respect of the products.

4B.—(1) Where the licence relates to products to which Chapters II to V of the 1965 Directive apply, the licence holder shall keep records, which may be in the form of invoices or on computer or in any other form, giving the following information in respect of such products which have been received or dispatched—

(a) the date of receipt and of dispatch;

(b) the name of the products;

(c) the quantity of the products received or dispatched;

(d) the name and address of the person from whom or to whom the products are sold or supplied, as appropriate.

(2) The records referred to in sub-paragraph (1) above shall be made available for inspection by any person duly authorised in writing by the licensing authority for a period of five years after the date of receipt or dispatch.".

(3) After paragraph 7 of Schedule 3 there shall be inserted the following paragraphs—

"**7A.**—(1) Where the licence relates to products to which Chapters II to V of the 1965 Directive apply, the licence holder shall at all times have at his disposal the services of a person (in this paragraph called a "responsible person") who possesses, in the opinion of the licensing authority—

(a) knowledge of the activities to be carried out and of the procedures to be performed under the licence which is adequate for performing the functions of the responsible person, and

(b) experience in those activities and procedures which is adequate for those purposes.

(**5**) OJ No. 22, 9.2.1965, p. 369/65; the relevant amending Directive is Article 1(3) of 89/341/EEC (OJ No. L142, 25.5.1989, p. 11).
(**6**) OJ No. L147, 9.6.1975, p. 13.
(**7**) OJ No. L142, 25.5.1989, p. 14.
(**8**) OJ No. L142, 25.5.1989, p. 16.
(**9**) OJ No. L181, 28.6.1989, p.44

(2) The functions of the responsible person shall be to ensure that the conditions under which the licence has been granted have been, and are being, complied with and that the quality of the products is being maintained in accordance with the requirements of the appropriate product licences.

(3) The provisions of sub-paragraphs (5) and (6) of paragraph 8 of this Schedule shall apply in relation to a responsible person as they apply in relation to a qualified person within the meaning of that paragraph, but as though the references to—

(a) the provisions of Articles 23 and 24 of the Second Council Directive as respects qualifications and experience were to the provisions of sub-paragraphs (1) and (2) of this paragraph, and

(b) to sub-paragraph (3) of paragraph 8 were to sub-paragraph (2) of this paragraph.

7B. Where the licence relates to products to which Chapters II to V of the 1965 Directive apply, the licence holder shall obtain supplies of such products only from—

(a) any person who is the holder of a manufacturer's licence or a wholesale dealer's licence which relates to those products; or

(b) any person who holds an authorisation granted by a competent authority of a member State other than the United Kingdom authorising the manufacture of such products or the distribution by way of wholesale dealing of such products.

7C.—(1) Where the licence relates to products to which Chapters II to V of the 1965 Directive apply, the licence holder shall distribute them by way of wholesale dealing only to—

(a) the holder of a wholesale dealer's licence which relates to those products; or

(b) the holder of an authorisation granted by the competent authority of a member State other than the United Kingdom authorising the supply of those products by way of wholesale distribution; or

(c) any person who may lawfully sell those products by retail or may lawfully supply them in circumstances corresponding to retail sale; or

(d) any person who may lawfully administer those products.

(2) Where supply is made pursuant to paragraph (1)(c) above, the licence holder shall enclose with the products a document which makes it possible to ascertain—

(a) the date on which the transaction took place;

(b) the name and pharmaceutical form of the products;

(c) the quantity of products supplied;

(d) the names and addresses of the persons from whom the products were supplied.".

Signed by authority of the Secretary of State for Health

Brian Mawhinney
Minister of State,
Department of Health

22nd March 1993

David Hunt
22nd March 1993 Secretary of State for Wales

Fraser of Carmyllie
22nd March 1993 Minister of State, Scottish Office

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on

L.S.

John Selwyn Gummer
24th March 1993. Minister of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on

L.S.

F.A. Elliott
22nd March 1993. Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on

L.S.

W.J. Hodges
22nd March 1993. 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 1971 Regulations") by implementing in part Council Directive 92/25/EEC (OJNo. L113, 30.4.92, p. 1) ("the Directive") which concerns the wholesale distribution of medicinal products for human use.

The Regulations insert new requirements into the 1971 Regulations for holders of wholesale dealer's licences which relate to products to which the Chapters II to V of the 1965 Directive apply (a definition of which is inserted in regulation 2). In particular, such persons are required to—

- institute an emergency plan to ensure the effectiveness of any recall of such products (regulation 3(2), article 6(d) of the Directive);
- keep specified records of products received or dispatched (regulation 3(2), articles 6(e) and 8 of the Directive) which must be kept for five years (article 6(f) of the Directive);
- specify the persons from whom such products may be obtained and to whom such products may be supplied (regulation 3(3), article 6(b) and (c) of the Directive); and
- specify that the licence shall name a person as responsible for ensuring that the conditions of the licence are being adhered to (regulation 3(3), article 5(b) of the Directive).