The Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Amendment Regulations 1993 / [Department of Health [and others]].

Contributors

Great Britain.
Great Britain. Laws, etc. (Statutory Instruments : 1993).
Great Britain. Department of Health.

Publication/Creation

London : H.M.S.O., 1993.

Persistent URL

https://wellcomecollection.org/works/vj7xp9tn

License and attribution

Wellcome Collection
183 Euston Road
London NW1 2BE UK
T +44 (0)20 7611 8722
E library@wellcomecollection.org
https://wellcomecollection.org

STATUTORY INSTRUMENTS

1993 No. 832

MEDICINES

The Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) 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 sections 18 and 129(1) of the Medicines Act 1968**(a)** or, as the case may be, those conferred by the said provisions and now vested in them**(b)** 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**(c)**, hereby make the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Amendment Regulations 1993, and shall come into force on 14th April 1993.

(2) In these Regulations, "the principal Regulations" means the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations 1971**(d)**.

Amendment of regulation 2 of the principal Regulations

2. In paragraph (1) of regulation 2 of the principal Regulations (interpretation), after the definition of "imported ready-made veterinary drug" there shall be inserted the following–

> " "member" in the expression "member State" means a member of the European Economic Community;

(a) 1968 c.67. The word "prescribed" in section 18(1) is defined in section 132(1) as amended. The expression "the Ministers" used in section 129(1) is defined in section 1(1) of that Act as amended.

(b) 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).

(c) *See* section 129(6) of the Medicines Act 1968.

(d) S.I. 1971/974; the relevant amending instruments are S.I. 1977/1052, 1978/1140, 1983/1725.

" "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(**a**), Article 34 of Council Directive 75/319/EEC(**b**), Article 1 of Council Directive 89/342/EEC(**c**), Article 1 of Council Directive 89/343/EEC(**d**) and Article 1 of Council Directive 89/381/EEC(**e**), Chapters II to V of Council Directive 65/65/EEC apply;".

Amendment of Schedule 2 to the principal Regulations

3. Schedule 2 to the principal Regulations (particulars required on an application for the grant of a wholesale dealer's licence) shall be amended by inserting after paragraph 8 the following paragraphs–

"**8A.** Where the licence is to relate to products to which Chapters II to V of the 1965 Directive apply, the name and address and degrees, diplomas or qualifications of a responsible person who is to carry out the functions specified in paragraph 7A(2) of Schedule 3 to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**f**) (in this and the following paragraph referred to as "the Standard Provisions Regulations").

8B. Where the licence is to relate to products to which Chapters II to V of the 1965 Directive apply, details of an emergency plan which satisfies the requirements of paragraph 4A of Schedule 3 to the Standard Provisions Regulations.

8C. Where the licence is to relate to products to which Chapters II to V of the 1965 Directive apply, a statement of any arrangements for keeping records, either in the form of invoices or on computer or in any other form, relating to all products received or dispatched.".

Signed by authority of the Secretary of State for Health

Brian Mawhinney
22nd March 1993 — Minister of State, Department of Health

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 24th March 1993.

L.S.

John Selwyn Gummer
Minister of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 22nd March 1993.

L.S.

F. A. Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 22nd March 1993.

L.S.

W. J. Hodges
Permanent Secretary

(**a**) 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).
(**b**) OJ No. L147, 9.6.1975, p. 13.
(**c**) OJ No. L142, 25.5.1989, p. 14.
(**d**) OJ No. L142, 25.5.1989, p. 16.
(**e**) OJ No. L181, 28.6.1989, p. 44.
(**f**) S.I. 1971/972. The relevant amending instrument is S.I. 1993/833.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations 1971 ("the 1971 Regulations") so implementing in part Council Directive 92/25/EEC (OJ No. L113, 30.4.92, p. 1) ("the Directive") which concerns the wholesale distribution of medicinal products for human use which are marketed within the European Community.

The Regulations insert a new requirement into the 1971 Regulations requiring applicants for wholesale dealer's licences which relate to products to which Chapters II to V of the 1965 Directive apply (a definition of which is inserted by regulation 2) to give the name and address of a responsible person who is to oversee wholesaling operations. (regulation 3, article 5(b) of the Directive).

Such applicants are also required by the amendments made by these Regulations to submit details of an emergency plan to be instituted where products are recalled (article 6(d) of the Directive) and of arrangements for keeping records relating to products received or dispatched (article 6(e) of the Directive).

STATUTORY INSTRUMENTS

1993 No. 832

MEDICINES

The Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Amendment Regulations 1993

ISBN 0-11-033832-4

9 780110 338323

£1.10 net

Printed in the United Kingdom for HMSO
879 WO852 C14 3/93 547/5 4235 228110 931323