The Medicines Act 1968 (Amendment) Regulations 1993 / [Departmet of Health].

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

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STATUTORY INSTRUMENTS

1993 No. 834

MEDICINES

The Medicines Act 1968 (Amendment) Regulations 1993

Made - - - -	*22nd March 1993*
Laid before Parliament	*24th March 1993*
Coming into force	*14th April 1993*

The Secretary of State for Health, in exercise of the powers conferred on her by section 2(2) of the European Communities Act 1972**(a)**, being designated for the purposes of that section in relation to medicinal products**(b)**, hereby makes the following Regulations–

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines Act 1968 (Amendment) Regulations 1993 and shall come into force on 14th April 1993.

(2) In these Regulations "the Act" means the Medicines Act 1968**(c)**.

Section 8 of the Act—manufacture and wholesale dealing

2.—(1) Section 8 of the Act (provisions as to manufacture and wholesale dealing) is amended as follows.

(2) At the beginning of subsection (3) there is inserted "Subject to subsection (3C) of this section,".

(3) In subsection (3) for the words from "licence granted" onwards there is substituted "wholesale dealer's licence".

(4) After that subsection there is inserted–

"(3A) Without prejudice to the generality of subsection (3) of this section but subject to subsection (3C), no person shall, in the course of a business carried on by him, distribute by way of wholesale dealing a product to which Chapters II to V of the 1965 Directive apply except in accordance with a wholesale dealer's licence.

(3B) Distribution of such a product by way of wholesale dealing shall not be taken to be in accordance with a wholesale dealer's licence unless, in particular, it occurs in the course of a business which is carried on at a place or places specified in the licence.

(3C) The restrictions imposed by subsections (3) and (3A) of this section do not apply to anything done in relation to a product to which Chapters II to V of the 1965 Directive apply by the holder of a manufacturer's licence in respect of it.".

(a) 1972 c.68.
(b) S.I. 1972/1811.
(c) 1968 c.67. Subsections (3) and (4) of section 8 have been amended by regulation 3(2) of S.I. 1977/1050, regulation 3 of S.I. 1983/1724 and regulation 3(2) and (3) of S.I. 1992/604, which also inserted subsections (5) and (6).

(5) After subsection (6) there is added–

"(7) In this section any reference to distribution of a product by way of wholesale dealing is a reference to–

(a) selling or supplying it, or

(b) procuring, holding or exporting it for the purposes of sale or supply,

to a person who receives it for the purposes of–

(i) selling or supplying it, or

(ii) administering it or causing it to be administered to one or more human beings,

in the course of a business carried on by that person.

(8) In this Act any reference to a wholesale dealer's licence is a reference to a licence granted for the purposes of subsection (3) or (3A) of this section.".

Section 10 of the Act–exemptions for pharmacists

3. In section 10(7) of the Act (exemptions for pharmacists), after "8(3)" there is inserted "or (3A)".

Section 14 of the Act—exemptions for re-exports

4. In section 14 of the Act (exemptions for re-exports)–

(a) at the beginning of that section (which becomes subsection (1)) there is inserted "Subject to subsection (2) of this section,"; and

(b) at the end of the section there is added–

"(2) Section 8(3A) of this Act applies to the exportation, or the sale for exportation, of any product to which Chapters II to V of the 1965 Directive apply if it is, or is to be exported to a member State.".

Amendment of section 48 of the Act–postponement of restrictions in relation to exports

5. In section 48(1) of the Act (postponement of restrictions in relation to exports), for "the next following section," there substituted "sections 49 and 49A of this Act,".

New section 49A of the Act–special provisions in respect of exporting certain products

6. After section 49 of the Act (special provisions in respect of exporting certain products) there is inserted–

"**Special provisions in respect of exporting certain products to member States**

49A. Nothing in subsection (1) of section 48 of this Act shall affect the operation of section 8(3A) of this Act in relation to the exportation of a product, or the sale or supply of a product which involves, or is for the purposes of, the exportation of the product if–

(a) it is a product to which Chapters II to V of the 1965 Directive apply; and

(b) the exportation is, or is to be, to a member State.".

Section 92 of the Act–scope of Part VI (advertising)

7. In section 92(4)(b) of the Act (scope of Part VI) for "subsection (3) of section 8" there is substituted ", subsection (3) or (3A) of section 8".

Virginia Bottomley
Secretary of State for Health

22nd March 1993

EXPLANATORY NOTE

(This Note is not part of the Regulations)

These Regulations amend the Medicines Act 1968 ("the Act") to implement 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 EC").

In particular, the Regulations amend the Act so as to provide (by new subsections (3A), (7) and (8) inserted in section 8 of the Act by regulation 2) that the distribution by way of wholesale dealing of a product to which Chapters II to V of the 1965 Directive apply requires a wholesale dealer's licence (article 3.1 of the Directive). "The 1965 Directive" is a term which, by virtue of regulation 3 of the Medicines Act 1968 (Amendment) (No. 2) Regulations 1992 (S.I. 1992/3271), is now defined in section 132(1) of the At. The new subsections (3B) and (3C) of section 8 inserted by regulation 2(4) provide that distribution by way of wholsale dealing of products to which Chapters II to V of the 1965 Directive apply is authorised by a wholesale dealer's licence only where it occurs in the course of a business carried on at a place specified in the licence (article 3.1 of the Directive), and that the holder of a manufacturer's licence for such a product does not require a wholesale dealer's licence for the wholesale distribution of that product (article 3.3 of the Directive).

Regulation 4 amends section 14 of the Act to require a wholesale dealer's licence for exportation to a member State of imported products to which Chapters II to V of the 1965 Directive apply (articles 1.2 and 3.1 of the Directive).

Regulation 6 inserts a new section 49A of the Act which applies the requirement for a wholesale dealer's licence to the export to member States of the EC of products to which Chapters II to V of the 1965 Directive apply (articles 1.2 and 3.1 of the Directive).

Regulations 3 and 7 make minor amendments to the Act consequential on the changes to section 8 of the Act.

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ISBN 0-11-033834-0

9 780110 338347

£1.10 net

Printed in the United Kingdom for HMSO
879 WO850 C14 3/93 547/5 4235 228110 931321