STATUTORY INSTRUMENTS

1994 No. 3144

The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994

Consequential and other amendments of the Act and the Medicines Act 1971

9.—(1) —Sections 3 and 4 of the Act shall have effect as if any reference to the Act included a reference to these Regulations.

(2) Section 7 of the Act (dealing with medicinal products and product licences) shall not apply in relation to relevant medicinal products.

(3) Section 23 of the Act (special provisions as to the effect of manufacturer's licence) shall have effect as if any reference in subsection (1) to a product licence included a reference to a marketing authorization.

(4) Section 58A of the Act (requirement to specify certain products for human use as prescription-only products) shall have effect as if in subsection (1)—

(a) the reference to section 58(1) of the Act included a reference to section 60(1) of the Act;

(b) the reference to a product licence included a reference to a marketing authorization;

(c) the reference to the descriptions or classes specified for the purposes of section 58 of the Act included a reference to the descriptions or classes specified in regulations under section 60 of the Act.

(5) Section 59 of the Act (special provisions in relation to new medicinal products) shall have effect as if—

(a) any reference to a product licence granted under Part II of the Act included a reference to a marketing authorization granted under these Regulations; and

(b) any reference to a product licence included a reference to such an authorization.

(6) Section 61 of the Act (special restrictions on persons to be supplied with medicinal products) shall have effect as if the reference to a product licence included a reference to a marketing authorization.

(7) Section 92 of the Act (scope of Part VI) shall have effect as if—

(a) any reference in subsection (4) to a licence under Part II of the Act included a reference to a marketing authorization; and

(b) the reference in that subsection to being engaged, in relation to medicinal products of the description in question, in any such activities as are referred to in that subsection included a reference to being engaged in putting medicinal products of that description on the market.

(8) Section 103 of the Act (construction of references to specified publications) shall have effect as if any reference in subsection (2) to a licence granted under the Act included a reference to a marketing authorization.

(9) The following provisions of the Act, namely—

(a) the provisions amended by paragraphs (3) to (8); and

(b) the other provisions of Parts III, VI and VII of the Act,

shall have effect as if all relevant medicinal products were medicinal products for the purposes of the Act (whether or not they would otherwise be so).

(10) In relation to any medicinal product to which section 58A of the Act applies by virtue of paragraph (4) and in respect of which a Community marketing authorization has been granted—

(a) that section shall have effect as if subsections (3) and (4) were omitted;

(b) section 58 of the Act (medicinal products on prescription only) shall have effect as if subsection (6) were omitted;

(c) section 60 of the Act (restricted sale, supply and administration of certain medicinal products) shall have effect as if subsection (7) were omitted;

(d) each of those sections shall have effect subject to the provisions of paragraph (4) of regulation 8 above; and

(e) section 129 of the Act (orders and regulations) shall have effect as if subsection (6) were omitted.

(11) The provisions of the Trade Description Act 1968(**1**) shall apply to the application of a trade description to goods subject to a marketing authorization in the same way as, by virtue of section 2(5)(b) of that Act, they apply to the application of a trade description to goods subject to any provision made under Part V of the Act.

(12) Section 1 of the Medicines Act 1971(**2**) (fees payable for purposes of Part II of the Act) shall have effect as if—

(a) in subsection (1), the reference to any application in pursuance of the Act for a licence under Part II of the Act or for the variation or renewal of such a licence included a reference to any application under these Regulations for a marketing authorization or for the variation or renewal of such an authorization; and

(b) in subsection (2)(b), any reference to a licence under Part II of the Act included a reference to a marketing authorization under these Regulations.

(13) Section 19 of the Consumer Protection Act 1987(**3**) (interpretation of Part II) shall have effect as if in subsection (1) in the definition of "licensed medicinal product", the reference to any medicinal product within the meaning of the Medicines Act 1968 in respect of which a product licence within the meaning of that Act is for the time being in force, included a reference to a relevant medicinal product in respect of which a United Kingdom marketing authorisation under these Regulations or a Community marketing authorisation is for the time being in force.

(14) Section 1 of the Food Safety Act 1990(**4**) (meaning of "food" and other basic expressions) shall have effect as if in paragraph (d)(i) of subsection (2), the reference to medicinal products within the meaning of the Medicines Act 1968 in respect of which product licences within the meaning of that Act are for the time being in force, included a reference to relevant medicinal products in respect of which United Kingdom marketing authorizations under these Regulations or Community marketing authorizations are for the time being in force.

(**1**) 1968 c. 29; section 2(5) was amended by the Medicines Act 1968, Schedule 5, paragraph 16.
(**2**) 1971 c. 69.
(**3**) 1987 c. 43.
(**4**) 1990 c. 16.