Medicines Act 1968

1968 CHAPTER 67

PART V

CONTAINERS, PACKAGES AND IDENTIFICATION OF MEDICINAL PRODUCTS

85 Labelling and marking of containers and packages.

(1) The appropriate Ministers may make regulations imposing such requirements as, for any of the purposes specified in subsection (2) of this section, they consider necessary or expedient with respect to any of the following matters, that is to say—

(a) the labelling of containers of medicinal products;

(b) the labelling of packages of medicinal products;

(c) the display of distinctive marks on containers and packages of medicinal products.

(2) The purposes referred to in the preceding subsection are—

(a) securing that medicinal products are correctly described and readily identifiable;

(b) securing that any appropriate warning or other appropriate information or instruction is given, and that false or misleading information is not given, with respect to medicinal products;

(c) promoting safety in relation to medicinal products.

(3) No person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, any medicinal product in such circumstances as to contravene any requirements imposed by regulations under this section which are applicable to that product.

(4) In so far as any such requirements relate to the labelling or marking of containers of medicinal products, a person who, in the course of a business carried on by him, sells or supplies a medicinal product to which the requirements are applicable without its being enclosed in a container shall, except in so far as the regulations otherwise provide, be taken to contravene those requirements as if he had sold or supplied it in a container not complying with those requirements.

(5) Without prejudice to the preceding provisions of this section, no person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, a medicinal product of any description in a container or package which is labelled or marked in such a way that the container or package—

(a) falsely describes the product, or

(b) is likely to mislead as to the nature or quality of the product or as to the uses or effects of medicinal products of that description.

Modifications etc. (not altering text)

C1 Pt. V (ss. 85–91) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C2 Ss. 85–88, 91 extended by S.I. 1984/187, **art. 2**

C3 S. 85 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**

86 Leaflets.

(1) The appropriate Ministers may make regulations imposing such requirements as, for any of the purposes specified in section 85(2) of this Act, they consider necessary or expedient with respect to leaflets relating to medicinal products which are supplied, or are intended to be supplied, with the products, whether by being enclosed in containers or packages of the products or otherwise.

(2) No person shall, in the course of a business carried on by him, supply with any medicinal product, or have in his possession for the purpose of so supplying, a leaflet which contravenes any requirements imposed by regulations under this section which are applicable to that leaflet.

(3) Without prejudice to the preceding provisions of this section, no person shall, in the course of a business carried on by him, supply with a medicinal product of any description, or have in his possession for the purpose of so supplying, a leaflet which—

(a) falsely describes the product, or

(b) is likely to mislead as to the nature or quality of the product or as to the uses or effects of medicinal products of that description.

[F1(4) No person shall, in the course of a business carried on by him, supply a product to which **[**F2the 2001 Directive applies**]**, unless—

(a) a leaflet enclosed in, or supplied with, the container or package of the product, or

(b) the container or package itself,

contains the particulars which a leaflet relating to the product is required by regulations under subsection (1) of this section to contain, and does so in the manner required by such regulations.**]**

Textual Amendments

F1 S. 86(4) inserted (13.2.1994) by S.I. 1994/276, **reg. 7(1)** (with reg. 7(2))(which S.I. revoked and replaced defective S.I. 1994/101 before the latter S.I. came into force)

F2 Words in s. 86(4) substituted (28.2.2002) by S.I. 2002/236, **reg. 2(a)(vi)**

Modifications etc. (not altering text)

C4 Pt. V (ss. 85–91) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C5 Ss. 85–88, 91 extended by S.I. 1984/187, **art. 2**
C6 S. 86 applied (with modifications) (3.4.1992) by S.I. 1992/605, reg. 2(1)(2), **Sch.**
S. 86 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**

87 Requirements as to containers.

(1) The appropriate Ministers may make regulations prohibiting the sale or supply of medicinal products otherwise than in containers which comply with such requirements as those Ministers consider necessary or expedient for any of the purposes specified in section 85(2) of this Act, or for the purpose of preserving the quality of the products, and in particular, may by the regulations require such containers to be of such strength, to be made of such materials, and to be of such shapes or patterns, as may be prescribed.

(2) No person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, any medicinal product in such circumstances as to contravene any requirements imposed by regulations under this section which are applicable to that product.

Modifications etc. (not altering text)
C7 Pt. V (ss. 85–91) extended with modifications by S.I. 1985/1403, **art. 3(1)**
C8 Ss. 85–88, 91 extended by S.I. 1984/187, **art. 2**

88 Distinctive colours, shapes and markings of medicinal products.

(1) Regulations made by the appropriate Ministers may impose such requirements as, for any of the purposes specified in section 85(2) of this Act, those Ministers consider necessary or expedient with respect to any one or more of the following matters, that is to say—

(a) the colour of the products;

(b) the shape of the products; and

(c) distinctive marks to be displayed on the products.

(2) Regulations made under this section may provide that medicinal products of any such description, or falling within any such class, as may be specified in the regulations shall not except in such circumstances (if any) as may be so specified, be of any such colour or shape, or display any such mark, as may be so specified.

(3) No person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, any medicinal product which contravenes any requirements imposed by regulations under this section.

Modifications etc. (not altering text)
C9 Pt. V (ss. 85–91) extended with modifications by S.I. 1985/1403, **art. 3(1)**
C10 Ss. 85–88, 91 extended by S.I. 1984/187, **art. 2**

89 Display of information on automatic machines.

(1) Regulations made by the appropriate Ministers may impose such requirements as they consider necessary or expedient with respect to the display on automatic machines of information relating to medicinal products offered or exposed for sale by means of such machines.

(2) No person shall offer or expose for sale any medicinal product by means of an automatic machine in such circumstances as to contravene any requirements imposed by regulations under this section which are applicable to that product.

Modifications etc. (not altering text)
C11 Pt. V (ss. 85–91) extended with modifications by S.I. 1985/1403, **art. 3(1)**

90 Provisions as to medicated animal feeding stuffs.

(1) The provisions of subsections (1) to (4) of section 85, subsections (1) and (2) of section 86, and section 87 of this Act shall have effect in relation to animal feeding stuffs in which medicinal products have been incorporated as if in those provisions any reference to the appropriate Ministers were a reference to the Agriculture Ministers and any reference to medicinal products were a reference to animal feeding stuffs in which medicinal products have been incorporated.

(2) Without prejudice to the preceding subsection, but subject to the next following subsection, no person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, any animal feeding stuff in which a medicinal product of any description has been incorporated, which is in a container or package labelled or marked in such a way that the container or package—

(a) falsely describes the animal feeding stuff in so far as its composition results from the incorporation of the medicinal product in it, or

(b) is likely to mislead as to the nature or quality of the animal feeding stuff in so far as its composition so results, or

(c) is likely to mislead as to the uses or effects of animal feeding stuffs in which medicinal products of the description in question have been incorporated, in so far as any such uses or effects are attributable to the incorporation of such medicinal products;

and no person shall, in the course of a business carried on by him, supply with any such animal feeding stuff, or have in his possession for the purpose of so supplying, a leaflet which falsely describes the animal feeding stuff, or is likely to mislead, as mentioned in paragraph (a), paragraph (b) or paragraph (c) of this subsection.

(3) For the purposes of subsection (2) of this section no account shall be taken—

[[F3](a) of any mark which is made on a container or package in pursuance of Part IV of the [M1]Agriculture Act 1970; or

(b) of any statement which, in pursuance of that Part, is made in any leaflet supplied, or intended to be supplied, with any material.**]**

(4) Section 130(10) of this Act shall have efect with the necessary modifications for the purpose of subsection (2)(c) of this section.

Textual Amendments

F3 S. 90(3)(a)(b) substituted by Agriculture Act 1970 (c. 40), **s. 87(4)**

Modifications etc. (not altering text)

C12 Pt. V (ss. 85–91) extended with modifications by S.I. 1985/1403, **art. 3(1)**

Marginal Citations

M1 1970 c. 40.

91 Offences under Part V, and supplementary provisions.

(1) Subject to sections 121 and 122 of this Act, any person who contravenes the provisions of section 85(5), section 86(3) **[**[F4]or (4)**]** or section 90(2) of this Act shall be guilty of an offence and liable—

(a) on summary conviction, to a fine not exceeding £400;

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

(2) Any regulations made under this Part of this Act may provide that any person who contravenes the regulations, or who contravenes the provisions of section 85(3), section 86(2) or section 87(2) of this Act or any of those provisions as applied by section 90(1) of this Act, shall be guilty of an offence and—

(a) shall be liable on summary conviction to a fine not exceeding £400 or such lesser sum as may be specified in the regulations, and

(b) if the regulations so provide, shall be liable on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both.

(3) Without prejudice to the application of section 129(5) of this Act, any power to make regulations conferred by sections 85 to 87 of this Act may be exercised so as to impose requirements either in relation to medicinal products generally or in relation to medicinal products of a particular description, or falling within a particular class, specified in the regulations, and any power to make regulations conferred by those sections as applied by section 90(1) of this Act shall be exercisable in a corresponding way.

(4) In this Part of this Act "requirements" includes restrictions.

Textual Amendments

F4 Words in s. 91(1) inserted (13.2.1994) by S.I. 1994/276, **reg.8** (which S.I. revoked and replaced S.I. 1994/101 before the latter S.I. came into force)

Modifications etc. (not altering text)

C13 Pt. V (ss. 85–91) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C14 Ss. 85–88, 91 extended by S.I. 1984/187, **art. 2**

C15 S. 91 applied (with modifications) (3.4.1992) by S.I. 1992/605, reg. 2(1)(2), **Sch.**

C16 Criminal Justice Act 1982 (c. 48, SIF 39:1), **ss. 38** (increase of fines) and 46 (substitution of references to levels on the standard scale) apply (E.W.) and Criminal Procedure (Scotland) Act 1975 (c. 21, SIF 39:1), **ss. 289F**, 289G (increase of fines and substitution of references to levels on the standard scale)

apply (S.) and S.I. 1984/703 (N.I. 3), **art. 5** (substitution of references to levels on the standard scale) and art. 6 (increase of fines) apply (N.I.)

Status:
Point in time view as at 31/05/2005.

Changes to legislation:
Medicines Act 1968, Part V is up to date with all changes known to be in force on or before 12 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.