



# Medicines Act 1968

## 1968 CHAPTER 67

### PART VI

#### PROMOTION OF SALES OF MEDICINAL PRODUCTS

##### Modifications etc. (not altering text)

C1 Part VI (ss. 92-97) modified (1.1.1995) by [S.I. 1994/3144](#), [reg.9\(9\)](#)

## 92 Scope of Part VI.

- (1) Subject to the following provisions of this section, in this Part of this Act “advertisement” includes every form of advertising, whether in a publication, or by the display of any notice, or by means of any catalogue, price list, letter (whether circular or addressed to a particular person) or other document, or by words inscribed on any article, [<sup>F1</sup>or by means of a photograph, film, sound recording, broadcast or cable programme,], or in any other way, and any reference to the issue of an advertisement shall be construed accordingly.
- (2) Notwithstanding anything in the preceding subsection, in this Part of this Act “advertisement” does not include spoken words except—
  - (a) words forming part of a sound recording . . . <sup>F2</sup>, and
  - (b) words broadcast [<sup>F3</sup>or included in a cable programme service].
- (3) Except as provided by section 95 of this Act, for the purposes of this Part of this Act neither of the following shall be taken to constitute the issue of an advertisement, that is to say—
  - (a) the sale or supply, or offer or exposure for sale or supply, of a medicinal product in a labelled container or package;
  - (b) the supply, with a medicinal product of any description, of a leaflet relating solely to medicinal products of that description.

*Status: Point in time view as at 01/02/1991.*

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- (4) In this Part of this Act “commercially interested party”, in relation to medicinal products of any description, means any person who—
- (a) is the holder of a licence under Part II of this Act which is applicable to medicinal products of that description, or
  - (b) not being the holder of such a licence, is a person who, in the course of a business carried on by him, is engaged, in relation to medicinal products of that description, in any such activities as are mentioned in subsection (2) or subsection (3) of section 7 or in subsection (2) or subsection (3) of section 8 of this Act, or
  - (c) sells by retail any medicinal products of that description in the course of a business carried on by him,
- and any reference to the request or consent of a commercially interested party includes a reference to any request made or consent given by a person acting on behalf of a commercially interested party; and “relevant business” means any business which consists of or includes the sale or supply of medicinal products.
- (5) In this Part of this Act “representation” means any statement or undertaking (whether constituting a condition or a warranty or not) which consists of spoken words other than words falling within paragraph (a) or paragraph (b) of subsection (2) of this section, and any reference to making a representation shall be construed accordingly.
- [<sup>F4</sup>(6) In this section “film”, “sound recording”, “broadcast”, “cable programme”, “cable programme service”, and related expressions, have the same meaning as in Part I of the Copyright, Designs and Patents Act 1988 (copyright).]

#### Textual Amendments

- F1** Words substituted by [Copyright, Designs and Patents Act 1988 \(c. 48, SIF 67A\)](#), s. 303(1), [Sch. 7 para. 10\(2\)](#)
- F2** Words repealed by [Copyright, Designs and Patents Act 1988 \(c. 48, SIF 67A\)](#), s. 303(1)(2), [Sch. 7 para. 10\(1\)\(3\)\(a\)](#), [Sch. 8](#)
- F3** Words substituted by [Copyright, Designs and Patents Act 1988 \(c. 48, SIF 67A\)](#), s. 303(1), [Sch. 7 para. 10\(1\)\(3\)\(b\)](#)
- F4** S. 92(6) substituted by [Copyright, Designs and Patents Act 1988 \(c. 48, SIF 67A\)](#), s. 303(1), [Sch. 7 para. 10\(1\)\(4\)](#)

#### Modifications etc. (not altering text)

- C2** S. 92 extended by [S.I. 1984/187](#), [art. 2](#)

### 93 False or misleading advertisements and representations.

- (1) Subject to the following provisions of this section, any person who, being a commercially interested party, or at the request or with the consent of a commercially interested party, issues, or causes another person to issue, a false or misleading advertisement relating to medicinal products of any description shall be guilty of an offence.
- (2) Where a licence under Part II of this Act is in force which is applicable to medicinal products of a particular description, and, in accordance with the provisions of the licence, the purposes for which medicinal products of that description may be recommended to be used are limited to those specified in the licence, then,

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subject to the following provisions of this section, any person who, being a commercially interested party, or at the request or with the consent of a commercially interested party, issues, or causes another person to issue, an advertisement relating to medicinal products of that description which consists of or includes unauthorised recommendations shall be guilty of an offence.

- (3) Subject to the following provisions of this section, any person who in the course of a relevant business carried on by him, or while acting on behalf of a person carrying on such a business, makes a false or misleading representation relating to a medicinal product in connection with the sale, or offer for sale, of that product shall be guilty of an offence; and any person who, in the course of such a business or while acting on behalf of a person carrying on such a business, makes a false or misleading representation relating to medicinal products of a particular description—

- (a) to a practitioner for the purpose of inducing him to prescribe or supply medicinal products of that description, or
- (b) to a patient or client of a practitioner for the purpose of inducing him to request the practitioner to prescribe medicinal products of that description, or
- (c) to a person for the purpose of inducing him to purchase medicinal products of that description from a person selling them by retail,

shall be guilty of an offence.

- (4) Where in the circumstances specified in subsection (2) of this section any person, in the course of a relevant business carried on by him, or while acting on behalf of a person carrying on such a business,—

- (a) in connection with the sale, or offer for sale, of a medicinal product of the description in question, makes a representation relating to the product which consists of or includes unauthorised recommendations, or
- (b) for any such purpose as is specified in paragraphs (a) to (c) of subsection (3) of this section makes a representation relating to medicinal products of that description which consists of or includes unauthorised recommendations,

that person, subject to the following provisions of this section, shall be guilty of an offence.

- (5) Where a person is charged with an offence under this section, it shall be a defence for him to prove—

- (a) where the offence charged is under subsection (1) or subsection (3) of this section, that he did not know, and could not with reasonable diligence have discovered, that the advertisement or representation was false or misleading;
- (b) where the offence charged is under subsection (2) or subsection (4) of this section, that he did not know, and could not with reasonable diligence have discovered, that the recommendations made by the advertisement or representation were unauthorised recommendations.

- (6) Without prejudice to the last preceding subsection, where a person is charged with an offence under this section in respect of the issue of an advertisement, it shall be a defence for him to prove that he is a person whose business it is to issue or arrange for the issue of advertisements, and that either—

- (a) he received the advertisement for issue in the ordinary course of business and issued it, or arranged for it to be issued, either unaltered or without any alteration except in respect of lettering or lay-out, or
- (b) not being a commercially interested party, he received from a commercially interested party the information on which the advertisement was based and

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in the ordinary course of business prepared the advertisement in accordance with that information for issue at the request of that party, and (in either case) that he did not know and had no reason to suspect that the issue of the advertisement would amount to an offence under this section.

- (7) For the purposes of this section an advertisement (whether it contains an accurate statement of the composition of medicinal products of the description in question or not) shall be taken to be false or misleading if (but only if)—
- (a) it falsely describes the description of medicinal products to which it relates, or
  - (b) it is likely to mislead as to the nature or quality of medicinal products of that description or as to their uses or effects,
- and any reference in this section to a false or misleading representation shall be construed in a corresponding way.
- (8) The preceding provisions of this section shall have effect subject to section 121 of this Act.
- (9) Any person guilty of an offence under this section shall be 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.
- (10) In this section “unauthorised recommendations”, in relation to the circumstances specified in subsection (2) of this section, means recommendations whereby medicinal products of a description to which the licence in question is applicable are recommended to be used for purposes other than those specified in the licence.

**Modifications etc. (not altering text)**

- C3** S. 93 extended by S.I. 1984/187, art. 2  
 S. 93 applied (1.1.1995) by S.I. 1994/3142, reg. 18(2)  
 S.93 extended (with modifications) (14.2.1994) by S.I. 1994/105, reg. 19, Sch.4  
 S. 93 applied (31.3.1997) by S.I. 1997/322, reg. 34, Sch.5

**94 Advertisements requiring consent of holder of product licence.**

- (1) Where a product licence under this Act is in force which is applicable to medicinal products of a particular description, then, except with the consent of the holder of the licence,—
- (a) no commercially interested party (other than the holder of the licence) shall issue, or cause another person to issue, any advertisement relating to medicinal products of that description; and
  - (b) no person who is not a commercially interested party shall, at the request or with the consent of a commercially interested party, issue, or cause another person to issue, any such advertisement.
- (2) Subject to section 121 of this Act, any person who contravenes the preceding subsection shall be guilty of an offence and liable on summary conviction to a fine not exceeding [<sup>F5</sup>level 3 on the standard scale].

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#### Textual Amendments

- F5** Words substituted by virtue of (E.W.) [Criminal Justice Act 1982 \(c. 48, SIF 39:1\)](#), [ss. 38, 46](#), (S.) [Criminal Procedure \(Scotland\) Act 1975 \(c.21, SIF 39:1\)](#), [ss. 289F, 289G](#) and (N.I.) [S.I. 1984/703 \(N.I. 3\)](#), [arts. 5, 6](#)

#### Modifications etc. (not altering text)

- C4** [S. 94](#) extended (with modifications) (14.2.1994) by [S.I. 1994/105, reg. 19, Sch.4](#)  
[S. 94](#) applied (1.1.1995) by [S.I. 1994/3142, reg. 18\(2\)](#)  
[S. 94](#) applied (31.3.1997) by [S.I. 1997/322, reg. 34, Sch.5](#)

## 95 Powers to regulate advertisements and representations.

- (1) The appropriate Ministers may by regulations prohibit any one or more of the following, that is to say—
- (a) the issue of advertisements relating to medicinal products of a description, or falling within a class, specified in the regulations;
  - (b) the issue of advertisements likely to lead to the use of any medicinal product, or any other substance or article, for the purpose of treating or preventing a disease specified in the regulations or for the purpose of diagnosis of a disease so specified or of ascertaining the existence, degree or extent of a physiological condition so specified or of permanently or temporarily preventing or otherwise interfering with the normal operation of a physiological function so specified, or for the purpose of artificially inducing a condition of body or mind so specified;
  - (c) the issue of advertisements likely to lead to the use of medicinal products of a particular description or falling within a particular class specified in the regulations, or the use of any other substance or article of a description or class so specified, for any such purpose as is mentioned in paragraph (b) of this subsection;
  - (d) the issue of advertisements relating to medicinal products and containing a word or phrase specified in the regulations, as being a word or phrase which, in the opinion of the appropriate Ministers, is likely to mislead the public as to the nature or effects of the products or as to any condition of body or mind in connection with which the products might be used.
- (2) Where any regulations are made in accordance with paragraph (b), paragraph (c) or paragraph (d) of the preceding subsection, the regulations may prohibit the making of any representation likely to lead to the use of a medicinal product or other substance or article to which the regulations apply for a purpose specified in the regulations in accordance with paragraph (b) of that subsection, or containing a word or phrase specified in the regulations in accordance with paragraph (d) of that subsection, if the representation—
- (a) is made in connection with the sale or supply, or offer for sale or supply, of a medicinal product or other substance or article to which the regulations apply, or
  - (b) is made to a person for the purpose of inducing him to purchase such a medicinal product, substance or article from a person selling by retail medicinal products or other substances or articles to which the regulations apply, or

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- (c) in the case of medicinal products of a description to which the regulations apply, is made to a practitioner for the purpose of inducing him to prescribe or supply medicinal products of that description or is made to a patient or client of a practitioner for the purpose of inducing him to request the practitioner to prescribe medicinal products of that description.
- (3) Without prejudice to the preceding provisions of this section, the appropriate Ministers may by regulations impose such requirements as, for any of the purposes specified in the next following subsection, they consider necessary or expedient with respect to any one or more of the following matters, that is to say—
- (a) the particulars which advertisements relating to medicinal products must contain;
  - (b) the form of any such advertisements; and
  - (c) in the case of advertisements by way of cinematograph films or television, the duration for which, and the manner in which, any part of such an advertisement which contains particulars of a description specified in the regulations must be exhibited;
- and any such regulations may prohibit the use, in relation to medicinal products of a description specified in the regulations, of advertisements of any particular kind so specified.
- (4) The purposes referred to in subsection (3) of this section are—
- (a) securing that adequate information is given with respect to medicinal products;
  - (b) preventing the giving of misleading information with respect to such products;
  - (c) promoting safety in relation to such products.
- (5) Without prejudice to the application of section 129(5) of this Act, any prohibition imposed by regulations under this section may be a total prohibition or may be imposed subject to such exceptions as may be specified in the regulations.
- (6) Any regulations made under this section may provide that any person who contravenes the regulations 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.
- (7) Section 92(3) of this Act shall not have effect for the purposes of paragraphs (b) to (d) of subsection (1) of this section.

**Modifications etc. (not altering text)**

- C5** S. 95 extended by S.I. 1984/187, **art. 2**  
 S. 95 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**  
 S. 95. applied (31.3.1997), by S.I. 1997/322, **reg. 34, Sch.5**
- C6** **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.)

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## **96 Advertisements and representations directed to practitioners.**

- (1) On and after the relevant date, no advertisement relating to medicinal products of a particular description, other than a data sheet, shall be sent or delivered to a practitioner—
  - (a) by a commercially interested party, or
  - (b) by any person at the request or with the consent of a commercially interested party,unless the conditions specified in subsection (3) of this section are fulfilled.
- (2) On and after the relevant date, no representation likely to promote the use of medicinal products of a particular description referred to in the representation shall be made to a practitioner by a person carrying on a relevant business, or by a person acting on behalf of a person carrying on such a business, unless the conditions specified in subsection (3) of this section are fulfilled.
- (3) Those conditions are—
  - (a) that a data sheet relating to medicinal products of the description in question is sent or delivered to the practitioner with the advertisement, or is delivered to him at the time when the representation is made, or that such a data sheet has been sent or delivered to him not more than fifteen months before the date on which the advertisement is sent or delivered or the representation is made, and
  - (b) that the advertisement or representation is not inconsistent with the particulars contained in the data sheet.
- (4) For the purposes of this section the relevant date—
  - (a) in relation to medicinal products of any description to which neither subsection (2) nor subsection (3) of section 16 of this Act is applicable, is the first appointed day, and
  - (b) in relation to medicinal products of any description to which either of those subsections is applicable, is the date of expiry of the period of six months from the date (or, if more than one, the latest date) on which, by virtue of one or more orders under section 17 of this Act, those subsections cease (or, if only one of them is applicable, that subsection ceases) to have effect in relation to them.
- (5) Subject to section 121 of this Act, any person who contravenes subsection (1) or subsection (2) of this section shall be guilty of an offence, and, if he contravenes that subsection by not complying with the condition specified in paragraph (b) of subsection (3) of this section, shall be liable—
  - (a) on summary conviction, to a fine not exceeding £400, or
  - (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both,and, in any other case, shall be liable on summary conviction to a fine not exceeding [F6level 3 on the standard scale].
- (6) In this and the next following section “data sheet” means a document relating to medicinal products of a particular description, which is prepared by or on behalf of the holder of a product licence which is applicable to medicinal products of that description and which—
  - (a) complies with such requirements as to dimensions and form, as to the particulars to be contained in it, and as to the manner (whether in respect of type, size, colour or disposition of lettering or otherwise) in which any such

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particulars are to be so contained, as may be prescribed for the purposes of this subsection, and

- (b) does not contain any information relating to medicinal products of that description except the particulars so prescribed.

#### Textual Amendments

**F6** Words substituted by virtue of (E.W.) Criminal Justice Act 1982 (c.48, SIF 39:1), **ss. 38, 46** and (S.) Criminal Procedure (Scotland) Act 1975 (c. 21, SIF 39:1), **ss. 289F, 289G** and (N.I.) S.I. 1984/703 (N.I. 3), **arts. 5, 6**

#### Modifications etc. (not altering text)

**C7** S. 96 extended (with modifications) (14.2.1994) by S.I. 1994/105, reg. 19, **Sch.4**  
 S. 96 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**

### 97 Power for licensing authority to require copies of advertisements.

- (1) The licensing authority may serve on any person a notice requiring him, within such time as may be specified in the notice, to furnish to the licensing authority such number of copies (not exceeding twelve) as may be so specified of any advertisement (including any data sheet) relating to medicinal products, or to medicinal products of a description or falling within a class so specified, which he has issued, or has caused to be issued, within the period of twelve months ending with the date of service of the notice, and which he has so issued, or caused to be issued,—
- (a) being a commercially interested party, or
- (b) at the request or with the consent of a commercially interested party.
- (2) Any person who without reasonable excuse fails to comply with any requirement imposed on him by a notice under this section shall be guilty of an offence, and shall be liable on summary conviction to a fine not exceeding [<sup>F7</sup>level 3 on the standard scale].

#### Textual Amendments

**F7** Words substituted by virtue of (E.W.) Criminal Justice Act 1982 (c. 48, SIF 39:1), **ss. 38, 46** and (S.) Criminal Procedure (Scotland) Act 1975 (c.21, SIF 39:1), **ss. 289F, 289G** and (N.I.) S.I. 1984/703 (N.I. 3), **arts. 5, 6**

#### Modifications etc. (not altering text)

**C8** S. 97 extended by S.I. 1984/187, **art. 2**  
 S. 97 extended (14.2.1994) by S.I. 1994/105, reg. 19, **Sch.4**  
 S. 97 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**  
 S. 97 applied (31.3.1997) by S.I. 1997/322, reg. 34, **Sch.5**



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