
STATUTORY INSTRUMENTS

1994 No. 1933

MEDICINES

The Medicines (Monitoring of Advertising) Regulations 1994

<i>Made</i>	- - - -	<i>18th July 1994</i>
<i>Laid before Parliament</i>		<i>19th July 1994</i>
<i>Coming into force</i>	- -	<i>9th August 1994</i>

The Secretary of State, acting in exercise of the powers conferred on her by section 2(2) of the European Communities Act 1972⁽¹⁾, being designated for the purposes of that section in relation to medicinal products⁽²⁾, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Medicines (Monitoring of Advertising) Regulations 1994 and shall come into force on 9th August 1994.

Interpretation and application

2.—(1) In these Regulations—

“the 1968 Act” means the Medicines Act 1968⁽³⁾;

“the 1990 Act” means the Broadcasting Act 1990⁽⁴⁾;

“the Advertising Regulations” means the Medicines (Advertising) Regulations 1994⁽⁵⁾;

“the Commission” means the Independent Television Commission established by section 1(1) of the 1990 Act;

“complaints authority” means the Commission, the Radio Authority or the Welsh Authority, as the case may be;

“court”, in relation to England and Wales and Northern Ireland, means the High Court, and, in relation to Scotland, means the Court of Session;

“publication” in relation to an advertisement means the dissemination of that advertisement, whether orally, in writing, by means of television or radio broadcast, or in any other way, and “publish” shall be construed accordingly;

(1) 1972 c. 68.
(2) S.I.1972/1811.
(3) 1968 c. 67.
(4) 1990 c. 42.
(5) S.I. 1994/1932.

“Radio Authority” means the authority established by section 83(1) of the 1990 Act;
 “the Welsh Authority” has the same meaning as in section 56(1) of the 1990 Act;
 and expressions used in these Regulations which are used in any provision of the 1968 Act have, subject to paragraphs (2) and (3) and unless the context requires otherwise, the meaning which they bear in the 1968 Act.

(2) For the purposes of these Regulations, “advertisement” has the meaning assigned to it by section 92 of the 1968 Act, except that—

- (a) provided that it makes no product claim, reference material, a factual, informative statement or announcement, a trade catalogue or a price list shall not be taken to be an advertisement, and
- (b) an advertisement includes a representation,

and for the purposes of this paragraph, “representation” has the meaning assigned to it by section 92 of the 1968 Act, except that it does not include the making of a factual, informative statement or announcement which includes no product claim.

(3) In these Regulations “the Health Ministers” means the Ministers specified in section 1(1)(a) of the 1968 Act⁽⁶⁾ and in the case of anything falling to be done by them under these Regulations means any one of them acting alone or any two or more of them acting jointly.

(4) In the application of these Regulations to Scotland, for references to an injunction or an interlocutory injunction there shall be substituted references to an interdict or an interim interdict respectively.

(5) In these Regulations, unless the context requires otherwise, a reference to a regulation shall be construed as a reference to that regulation contained in these Regulations, and any reference in a regulation to a numbered paragraph shall be construed as a reference to the paragraph of that regulation bearing that number.

(6) These Regulations apply only to an advertisement for a product, substance or article for human use which is—

- (a) a medicinal product to which Chapters II to V of the 1965 Directive⁽⁷⁾ apply,
- (b) a substance or article—
 - (i) to which Chapters II to V of the 1965 Directive⁽⁷⁾ apply, and
 - (ii) specified in an order made under section 104 or section 105 of the 1968 Act, or in regulations made under section 2(2) of the European Communities Act 1972, which direct that Part VI or any section of that Part of the 1968 Act has effect in relation to such substance or article as that Part has effect in relation to medicinal products within the meaning of the 1968 Act, or
- (c) a homoeopathic medicinal product⁽⁸⁾ to which Council Directive 92/73/EEC⁽⁹⁾ applies which is marketed in the United Kingdom under a certificate of registration⁽¹⁰⁾ in accordance with the provisions of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994⁽¹¹⁾,

(6) Section 1(1)(a) was amended by article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388); in respect of Northern Ireland, see 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).

(7) The definition of “the 1965 Directive” in section 132(1) of the 1968 Act was amended by regulation 9 of S.I. 1994/ 276.

(7) The definition of “the 1965 Directive” in section 132(1) of the 1968 Act was amended by regulation 9 of S.I. 1994/ 276.

(8) The definition of “homoeopathic medicinal product” was inserted into section 7 of the 1968 Act by regulation 3(4) of S.I. 1994/276.

(9) OJ No. L297, 13.10.1992, p.8.

(10) The definition of “certificate of registration” was inserted into section 7 of the 1968 Act by regulation 3(4) of S.I. 1994/276.

(11) S.I. 1994/105, as amended by S.I. 1994/899.

but do not apply to an advertisement for a homoeopathic medicinal product in respect of which there is in force a product licence being a licence of right.

Proceedings

3.—(1) Proceedings under these Regulations shall be brought in England and Wales and in Northern Ireland in the High Court and, in Scotland, before the Court of Session.

(2) These Regulations are without prejudice to the availability of any criminal proceedings which may be taken under the 1968 Act or the Advertising Regulations.

(3) The Health Ministers (whether one of them acting alone or two or more of them acting jointly) may, in performing functions conferred on them by these Regulations, institute civil proceedings in their own name.

Complaints about advertisements

4.—(1) Subject to paragraph (2), the Health Ministers shall consider any complaint made to them, other than a complaint to which regulation 5 applies or which it is the duty of a complaints authority to consider under regulations 9(1) or 10(1), that an advertisement, whether or not it has yet been published, may be in breach of the Advertising Regulations.

(2) The Health Ministers shall not proceed with the consideration of any complaint which appears to them to be frivolous or vexatious.

(3) In exercising the powers conferred on them by these Regulations the Health Ministers shall have regard to all the interests involved and in particular the public interest.

Complaints about certain advertisements

5.—(1) This regulation applies to any complaint made to the Health Ministers, other than a complaint which it is the duty of a complaints authority to consider under regulations 9(1) or 10(1), that an advertisement, whether or not it has yet been published, may be in breach of any provision of regulation 9 of the Advertising Regulations (prohibition of certain material in advertisements to the public) or any regulation in Part IV of the Advertising Regulations (advertising to health professionals).

(2) Subject to paragraph (4), in relation to a complaint to which this regulation applies, where the Health Ministers and the complainant agree within a reasonable time that the provisions of this paragraph should apply, the Health Ministers shall select a body which appears to them to be a self-regulatory body which deals with complaints about advertisements of that type, shall refer the complaint to that body, and that body may consider the complaint.

(3) Subject to paragraph (4), the Health Ministers shall consider any complaint to which this regulation applies—

- (a) in the absence of any agreement within a reasonable time in accordance with paragraph (2), or
- (b) if, where there is such agreement, the body selected by the Health Ministers in accordance with paragraph (2) has not within a reasonable time dealt with the complaint adequately.

(4) Neither the Health Ministers nor the body selected by the Health Ministers in accordance with paragraph (2) shall proceed with the consideration of any complaint which appears to them or to it to be frivolous or vexatious.

Applications to the court by the Health Ministers

6. If, having considered in accordance with regulation 4(1) or 5(3) an advertisement about which a complaint has been made, or having considered an advertisement about which no complaint has been made, the Health Ministers consider that that advertisement is in breach of the Advertising Regulations, they may bring proceedings for an injunction (in which proceedings they may also apply for an interlocutory injunction) against any person appearing to them to be concerned or likely to be concerned with the publication of that advertisement.

Functions of the court

7.—(1) Before granting an injunction the court shall have regard to all the interests involved and in particular the public interest.

(2) An injunction may relate not only to a particular advertisement but to any advertisement in similar terms or likely to convey a similar impression.

(3) An injunction may prohibit the publication or further publication of an advertisement.

(4) In considering an application for an injunction the court may, either on the application of any party to the proceedings or of its own motion, require any person appearing to the court to be responsible for the publication of the advertisement to which the application relates to furnish the court within such time as it allows with evidence as to the accuracy of any factual claim made in the advertisement; and in deciding whether or not to make such a requirement the court shall have regard to the legitimate interests of any person who would be the subject of or affected by the requirement.

(5) If such evidence is not furnished to it in accordance with paragraph (4) or if it considers such evidence inadequate, the court may consider the factual claim inaccurate.

(6) The court shall not refuse to grant an injunction for lack of evidence that—

- (a) the publication or anticipated publication of the advertisement in question has given rise to loss or damage to any person, or
- (b) the person responsible for the advertisement intended it to be in breach of the Advertising Regulations, or failed to exercise proper care to prevent its being in breach of those Regulations.

(7) Where the court grants an injunction following an application under regulation 6, the court shall give reasons in detail for the granting of the injunction, and the Health Ministers shall communicate those reasons in writing to the person against whom the injunction has been granted, referring to any remedy available in the court and any time limit which must be met in order for any such remedy to be available.

Publication of decision and corrective statement

8.—(1) Where the court has granted an injunction (other than an interlocutory injunction) following an application under regulation 6, the Health Ministers may require any person against whom the injunction has been granted to publish within a specified time in such form as the Health Ministers consider adequate—

- (a) the decision, in full or in part, to grant the injunction, and
- (b) a corrective statement in relation to the advertisement in respect of which the injunction was granted.

(2) If any person fails within the time specified in paragraph (1) to publish any statement which the Health Ministers may require under the provisions of that paragraph, the Health Ministers may certify that failure to the court.

(3) Where a person's failure is certified in accordance with paragraph (2), the court may enquire into the matter.

(4) Where the court conducts an enquiry in accordance with paragraph (3) and is satisfied that a person has failed within the time specified in paragraph (1) to publish any statement which the Health Ministers may require under the provisions of that paragraph, it may, after—

- (a) hearing any witness produced against, or on behalf of, the person concerned, and
- (b) considering any statement offered in his defence,

deal with him in any manner that would be available to it had he been in contempt of court.

Complaints to the Commission and Radio Authority about certain broadcast advertisements

9.—(1) The Commission or the Radio Authority, as the case may be, shall consider any complaint made to it that any advertisement included or proposed to be included in a licensed service may be in breach of any provision of regulation 9 of the Advertising Regulations, unless the complaint appears to it to be frivolous or vexatious.

(2) In exercising the powers conferred on it by these Regulations the Commission or the Radio Authority, as the case may be, shall have regard to all the interests involved and in particular the public interest.

(3) In this regulation, “licensed service” means—

- (a) in relation to a complaint made to the Commission, a service in respect of which the Commission has granted a licence under Parts I or II of the 1990 Act, and
- (b) in relation to a complaint made to the Radio Authority, a service in respect of which the Radio Authority has granted a licence under Part III of the 1990 Act.

Complaints to the Welsh Authority about certain broadcast advertisements

10.—(1) The Welsh Authority shall consider any complaint made to it that any advertisement broadcast or proposed to be broadcast on S4C may be in breach of any provision of regulation 9 of the Advertising Regulations, unless the complaint appears to it to be frivolous or vexatious.

(2) In exercising the powers conferred on it by these Regulations the Welsh Authority shall have regard to all the interests involved and in particular the public interest.

(3) In this regulation, “S4C” has the same meaning as in section 57(1) of the 1990 Act.

Control by a complaints authority of certain broadcast advertisements

11.—(1) If, having considered a complaint about an advertisement in accordance with regulation 9(1) or 10(1), a complaints authority considers that the advertisement in question is in breach of any provision of regulation 9 of the Advertising Regulations, a complaints authority may—

- (a) in the case of the Commission, give directions under subsection (6) of section 9 of the 1990 Act for the purpose of preventing the publication or further publication of that advertisement, whether or not those directions are also for the purpose of securing that the provisions of the code referred to in that subsection are complied with,
- (b) in the case of the Radio Authority, give directions under subsection (6) of section 93 of the 1990 Act for the purpose of preventing the publication or further publication of that advertisement, whether or not those directions are also for the purpose of securing that the provisions of the code referred to in that subsection are complied with,
- (c) in the case of the Welsh Authority, refuse the publication or further publication of that advertisement.

(2) Directions referred to in paragraph (1)(a) or (b) may relate not only to a particular advertisement but to any advertisement in similar terms or likely to convey a similar impression.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

(3) A complaints authority shall not refuse to exercise its powers under paragraph (1) for lack of evidence that—

- (a) the publication or anticipated publication of the advertisement in question has given rise to loss or damage to any person, or
- (b) the person responsible for the advertisement intended it to be in breach of any provision of regulation 9 of the Advertising Regulations, or failed to exercise proper care to prevent its being in breach of any part of that regulation.

(4) A complaints authority shall give reasons in detail for its decision under paragraph (1), and shall communicate those reasons in writing to the person against whom action has been taken under that paragraph, referring to any remedy available in the court and any time limit which must be met in order for any such remedy to be available.

Signed by authority of the Secretary of State for Health

18th July 1994

Tom Sackville
Parliamentary Under Secretary of State
Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement Article 12 of Council Directive [92/28/EEC](#) (OJNo. L113, 30.4.92, p.13) (“the Directive”) concerning the advertising of medicinal products for human use by specifying procedures whereby persons or organisations may bring an advertisement which is inconsistent with the requirements of the Directive before an administrative authority competent either to decide on complaints or to institute civil proceedings in the High Court (or, in Scotland, the Court of Session).

For the purposes of these Regulations, “advertisement” has the same meaning as in section 92 of the Medicines Act 1968, with certain modifications to take account of article 1(3) and (4) of the Directive, and includes a representation (regulation 2(2)).

Regulation 2(6) provides that the Regulations apply to advertisements for medicinal products for human use to which Council Directive [65/65/EEC](#) applies (OJ No. 22, 9.2.1965, p.369/65), and also to advertisements for homoeopathic medicinal products marketed under a certificate of registration (implementing article 6(3) of Council Directive [92/73/EEC](#) (OJ No. L297, 13.10.1992, p.8)) (but not to advertisements for homoeopathic medicinal products marketed under a product licence of right).

Regulation 4 provides that it is the duty of the Health Ministers under the Medicines Act 1968 to consider complaints about advertisements for medicinal products for human use, except complaints to which regulations 5, 9 or 10 apply.

Where a complaint is made either that an advertisement is in breach of Part IV of the Medicines (Advertising) Regulations 1994 (advertising to health professionals), or that a non-broadcast advertisement is in breach of regulation 9 of those Regulations (prohibition of certain material in advertisements to the public), a self-regulatory body which deals with complaints about such advertisements, selected by the Health Ministers, may consider such complaint, if the complainant and the Health Ministers agree (regulation 5).

Regulation 6 provides that the Health Ministers may apply to the court for an injunction about a particular advertisement, to prevent its publication or further publication, and regulations 7 and 8 give details in relation to the granting of an injunction. If a final injunction is granted, the Health Ministers have power to require the publication of the decision and a corrective statement.

Regulations 9 and 10 provide that the Independent Television Commission, the Radio Authority or the Welsh Authority, as appropriate (statutory bodies given powers over advertisements by the Broadcasting Act 1990), has a duty to consider complaints that a broadcast advertisement may be in breach of regulation 9 of the Medicines (Advertising) Regulations 1994. Those bodies also have power under the Broadcasting Act 1990 to prevent transmission or further transmission of an advertisement (regulation 11).

These Regulations do not affect the availability of criminal proceedings where relevant in connection with the advertising of medicinal products for human use (regulation 3(2)).

The remaining parts of the Directive are implemented by the Medicines (Advertising) Regulations 1994, and these Regulations complete implementation of the Directive.