STATUTORY INSTRUMENTS

1999 No. 267

MEDICINES

The Medicines (Advertising and Monitoring of Advertising) Amendment Regulations 1999

Made - - - -	*5th February 1999*
Laid before Parliament	*8th February 1999*
Coming into force - -	*5th April 1999*

The Secretary of State, being a Minister designated for the purposes of section 2(2) of the European Communities Act 1972(**1**) in relation to medicinal products(**2**), in exercise of the powers conferred on him by the said section 2(2), and the Secretaries of State respectively concerned with health in England, in Wales and in Scotland and the Department of Health and Social Services for Northern Ireland, acting jointly, in exercise of the powers conferred upon them by sections 61 and 95(1), (3) and (6) of the Medicines Act 1968(**3**), or, as the case may be, powers conferred by the said provisions and now vested in them(**4**), and in each case of all other powers enabling them in that behalf, after consultation (in accordance with section 129(6) of the Medicines Act 1968) with such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations, hereby make the following Regulations:–

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Advertising and Monitoring of Advertising) Amendment Regulations 1999 and shall come into force on 5th April 1999.

(2) In these Regulations–

"the Advertising Regulations" means the Medicines (Advertising) Regulations 1994(**5**); and

"the Monitoring of Advertising Regulations" means the Medicines (Monitoring of Advertising) Regulations 1994(**6**).

(**1**) 1972 c. 68.
(**2**) S.I.1972/1811.
(**3**) 1968 c. 67; *see* section 1(2)(a) of the 1968 Act, which contains a definition of "the appropriate Ministers" which is relevant to the powers being exercised in the making of these Regulations.
(**4**) In the case of the Secretaries of State concerned with health in England and in Wales, by virtue of article 2(2) of and Schedule 1 to the Transfer of Functions (Wales) Order 1969; and in the case of the Department of Health and Social Services for Northern Ireland, by virtue of 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).
(**5**) S.I. 1994/1932; the relevant amending instruments are S.I. 1994/3144, S.I. 1996/1552.
(**6**) S.I. 1994/1933.

Amendment of regulation 2 of the Advertising Regulations

2. In regulation 2 of the Advertising Regulations (interpretation)–

(a) in paragraph (1)–

(i) after the definition of "name" there shall be inserted the following definition–

""persons qualified to prescribe or supply" includes persons, and employees of such persons, who in the course of their profession or in the course of a business may lawfully prescribe, sell by retail or supply in circumstances corresponding to retail sale relevant medicinal products;", and

(ii) in the definition of "relevant medicinal product" after the words "Directive apply" in paragraph (a) there shall be added the words "and accordingly includes products to which Title II of Council Regulation 2309/93(**7**) applies"; and

(b) after paragraph (3) there shall be inserted the following paragraph–

"(4) In these Regulations, "the Health Ministers" means the Ministers specified in section 1(1)(a) of the Act, and the functions of the Health Ministers under these Regulations may be performed by any one of them acting alone or any two or more of them acting jointly.".

Insertion of regulation 3A into the Advertising Regulations

3. After regulation 3 of the Advertising Regulations (prohibition of advertisements for unlicensed products) there shall be inserted the following regulation–

"**General principles**

3A.—(1) No person shall issue an advertisement relating to a relevant medicinal product unless that advertisement complies with the particulars listed in the summary of product characteristics.

(2) No person shall issue an advertisement relating to a relevant medicinal product unless that advertisement encourages the rational use of that product by presenting it objectively and without exaggerating its properties.

(3) No person shall issue a misleading advertisement relating to a relevant medicinal product.".

Amendment of regulation 4 of the Advertising Regulations

4. For paragraphs (c) and (d) of regulation 4 of the Advertising Regulations (duties of licence holders) there shall be substituted the following–

"(c) keep available for the Health Ministers, or communicate to them within such period as may be specified in a notice served by them on him, a sample of any advertisement for which he is responsible relating to that product, together with a statement indicating the persons to whom the advertisement is addressed, the method of dissemination and the date of first dissemination; and

(d) supply, within the period specified in a notice served by the Health Ministers on him, any information and assistance requested by them in order to carry out their functions under these Regulations or the Medicines (Monitoring of Advertising) Regulations 1994(**8**).".

(**7**) OJNo. L214, 24.8.93, p. 1.
(**8**) S.I. 1994/1933.

Substitution of regulation 12 of the Advertising Regulations

5. For regulation 12 of the Advertising Regulations (prohibition of supply of medicinal products to the public) there shall be substituted the following regulation–

"**Prohibition of supply of medicinal products to the public**

12. No person–

(a) being the holder of a marketing authorization; or

(b) in the course of a business carried on by him and consisting (wholly or partly) of manufacturing relevant medicinal products or of selling or supplying relevant medicinal products,

shall for a promotional purpose (whether a promotional purpose of his own or of a third party) sell or supply any relevant medicinal product to any member of the public.".

Amendment of heading to regulation 14 of the Advertising Regulations

6. For the heading to regulation 14 of the Advertising Regulations (advertisements to health professionals) there shall be substituted "**Advertising to persons qualified to prescribe or supply**".

Amendment of regulation 20 of the Advertising Regulations

7. In paragraph (1) of regulation 20 of the Advertising Regulations (medical sales representatives) after the words "qualified to prescribe" there shall be inserted the words "or supply".

Amendment of regulation 23 of the Advertising Regulations

8. In regulation 23 of the Advertising Regulations (offences)–

(a) in paragraph (1)–

(i) after "3(1)," there shall be inserted "3A,", and

(ii) after "10(1)," there shall be inserted "12,"; and

(b) after paragraph (2) there shall be added the following paragraph–

"(3) Notwithstanding that these Regulations were not made entirely under the Act, sections 107 to 109, section 110 except subsection (4), sections 111 to 116, section 118, section 119 and sections 121 to 127 of and Schedule 3 to the Act shall apply for the purposes of these Regulations as they apply for the purposes of the Act.".

Amendment of heading to Schedule 2 to the Advertising Regulations

9. For the heading to Schedule 2 to the Advertising Regulations (particulars to be contained in advertisements to health professionals) there shall be substituted "**PARTICULARS TO BE CONTAINED IN ADVERTISEMENTS TO PERSONS QUALIFIED TO PRESCRIBE OR SUPPLY**".

Amendment of regulation 2 of the Monitoring of Advertising Regulations

10. In paragraph (1) of regulation 2 of the Monitoring of Advertising Regulations (interpretation and application) in the definition of "publication" after the words "the dissemination" there shall be inserted the words "or issue".

Amendment of regulation 3 of the Monitoring of Advertising Regulations

11. In paragraph (1) of regulation 3 of the Monitoring of Advertising Regulations (proceedings) before the words "Proceedings under" there shall be inserted the words "Subject to regulation 13 and the Schedule to these Regulations,".

Addition of regulations 12 and 13 to the Monitoring of Advertising Regulations

12. After regulation 11 of the Monitoring of Advertising Regulations (control by a complaints authority of certain broadcast advertisements) there shall be added the following regulations–

"**Application of enforcement provisions of the 1968 Act**

12. Notwithstanding that these Regulations were not made under the 1968 Act, sections 107 to 109, section 110 except subsection (4), sections 111 to 116, section 118, section 119 and sections 121 to 127 of and Schedule 3 to the 1968 Act shall apply for the purposes of the Regulations as they apply for the purposes of the 1968 Act.

Scrutiny of certain published or proposed advertisements

13. The provisions of the Schedule to these Regulations (scrutiny of certain published or proposed advertisements) shall have effect.".

Addition of a Schedule to the Monitoring of Advertising Regulations

13. At the end of the Monitoring of Advertising Regulations there shall be added the following Schedule–

"SCHEDULE Regulation 13

SCRUTINY OF CERTAIN PUBLISHED OR PROPOSED ADVERTISEMENTS

Notices requiring copies of advertisements to be furnished to the Health Ministers

1. The Health Ministers may serve a notice in writing in respect of any relevant medicinal product or in respect of relevant medicinal products of any class or description on any person appearing to them to be concerned or likely to be concerned with the publication of an advertisement requiring that person–

(a) to furnish to the Health Ministers within such period as may be specified in the notice a copy of any advertisement which he has published or proposes to publish; or

(b) to furnish to the Health Ministers a copy of any advertisement which he proposes to publish and the notice shall specify–

(i) the number of days before the proposed publication date by which the advertisement shall be furnished, and

(ii) the period during which the requirement shall continue, such period not to exceed twelve months,

and that notice may require that person to refrain from publishing any advertisement required to be furnished under sub-paragraph (a) or (b) during such period as may be specified in the notice unless that notice has been withdrawn by the Health Ministers.

2. Where the Health Ministers serve a notice on a person under paragraph 1, the notice shall state the Health Ministers' reasons for requiring that person to furnish the advertisement and for requiring him (if the notice does) to refrain from publishing it.

"Minded to" notices in respect of determinations of breaches of the Advertising Regulations

3. If the Health Ministers, having considered an advertisement furnished to them in accordance with paragraphs 1(a) or 1(b) or otherwise obtained by them, are minded to make a determination that the advertisement, if published, would be in breach of the Advertising Regulations, they may serve a notice on any person appearing to them to be concerned or likely to be concerned with the publication of the advertisement stating–

(a) that they are minded to make a determination that the advertisement, if published, would be in breach of the Advertising Regulations;

(b) the reasons why they are minded to make that determination;

(c) that if such a determination is made, that person may be required to refrain from publishing that advertisement by a notice served under paragraph 5; and

(d) that the person on whom the notice is served has twenty-one days from the date of the notice in which to make written representations that the proposed determination should not be made,

and the notice may require that person to refrain from publishing that advertisement until the notice has been withdrawn by the Health Ministers.

Decisions that an advertisement would not be in breach

4. If, upon further consideration, in particular of any representations made to them under paragraph 3(d), the Health Ministers decide that the advertisement, if published, would not be in breach of the Advertising Regulations, they shall serve a notice on the person on whom they had previously served a notice under paragraph 3–

(a) informing him of that decision; and

(b) withdrawing the notice served in respect of that advertisement under paragraph 3.

Determinations that an advertisement would be in breach

5. If, upon further consideration, in particular of any representations made to them under paragraph 3(d), the Health Ministers make a determination that the advertisement, if published, would be in breach of the Advertising Regulations, they shall serve a notice on the person on whom they had previously served a notice under paragraph 3–

(a) stating the reasons for the determination;

(b) withdrawing the notice served in respect of that advertisement under paragraph 3,

and the notice may require him to refrain from publishing that advertisement.

Publication of the determination and a corrective statement

6. Where the Health Ministers have prohibited the publication of an advertisement under paragraph 5 and that advertisement has previously been published, they may require any person against whom the prohibition has been imposed to publish within a specified time in such form as the Health Ministers consider appropriate–

(a) the reasons for the determination (as notified to them by the Health Ministers under paragraph 5(a)), in full or in part (whichever the Health Ministers require); and

(b) a corrective statement in relation to the advertisement in respect of which the prohibition has been imposed.

Offences

7. Any person who fails to comply with any requirement imposed on him by a notice under paragraphs 1, 3 or 5 shall be guilty of an offence and shall be liable–

(a) on summary conviction, to a fine not exceeding level 5 on the standard scale,

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

8. Any person who fails to comply with any requirement imposed on him under paragraph 6 shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.".

Signed by authority of the Secretary of State for Health

Hayman
Parliamentary Under Secretary of State
1st February 1999 Department of Health

Signed by authority of the Secretary of State for Wales

Jon Owen Jones
Parliamentary Under Secretary of State Welsh
5th February 1999 Office

Signed by authority of the Secretary of State for Scotland

Sam Galbraith
Parliamentary Under Secretary of State Scottish
3rd February 1999 Office

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on

L.S.

D.C. Gowdy
4th February 1999. Permanent Secretary

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Advertising) Regulations 1994 ("the Advertising Regulations") and the Medicines (Monitoring of Advertising) Regulations 1994 ("the Monitoring of Advertising Regulations"). Those Regulations contain the legislative measures necessary for implementing Council Directive 92/28/EEC concerning the advertising of medicinal products for human use(**9**) ("the Advertising Directive"), and these Regulations make further provision relating to the implementation of that Directive.

Regulation 2 amends the interpretation provision of the Advertising Regulations, adding new definitions of "persons qualified to prescribe or supply" medicinal products and of "the Health Ministers", and clarifying the scope of the existing definition of "relevant medicinal products".

Regulation 3 inserts a new regulation 3A into the Advertising Regulations which sets out general principles relating to the advertising of relevant medicinal products. These principles are based on article 2(2) and (3) of the Advertising Directive.

Regulation 4 amends regulation 4 of the Advertising Regulations, including amongst the duties of holders of marketing authorizations responsibilities based on the first and fourth indents of article 13(2) of the Advertising Directive. These relate to samples of advertisements which must be kept available for the Health Ministers, and, to information and assistance which must be supplied to them to enable them to carry out their functions under the Advertising Regulations and the Monitoring of Advertising Regulations.

Regulation 5 contains a revised version of regulation 12 of the Advertising Regulations, extending the prohibition (based on article 3(6) of the Advertising Directive) on sale or supply to the public of relevant medicinal products for promotional purposes.

Regulations 6 and 9 change two of the headings in the Advertising Regulations to reflect more accurately the provisions to which they relate. Regulation 7 extends the application of regulation 20 of the Advertising Regulations to cover the activities of medical sales representatives who promote relevant medicinal products to persons qualified to supply such products. Regulation 8 contains technical amendments to the offences provision of the Advertising Regulations, making regulations 3A and 12 offences for the purposes of those Regulations and clarifying the applicability of the enforcement provisions of the Medicines Act 1968 to breaches of the Advertising Regulations.

Regulation 10 contains a minor modification to the definition of "publication" for the purposes of the Monitoring of Advertising Regulations, and regulation 11 contains a minor modification of regulation 3 of the Monitoring of Advertising Regulations which arises as a consequence of the new Schedule to those Regulations inserted by virtue of these Regulations.

Regulation 12 inserts two regulations into the Monitoring of Advertising Regulations: a regulation applying the enforcement provisions of the Medicines Act 1968 to breaches of the Monitoring of Advertising Regulations, and a regulation giving effect to the new Schedule inserted by virtue of these Regulations.

Regulation 13 inserts a new Schedule into the Monitoring of Advertising Regulations. The Schedule contains a new notices procedure relating to the scrutiny of published or proposed advertisements for relevant medicinal products. This procedure is to be used by the Health Ministers for determining whether or not the advertisements, if published, would be in breach of the Advertising Regulations.

(**9**) OJ No. L113, 30.4.92, p. 13.

There is an opportunity for written representations to be made to the Health Ministers before they reach their decision or determination. Breaches of the notices will, in certain circumstances, be offences.