STATUTORY INSTRUMENTS

1994 No. 1932

The Medicines (Advertising) Regulations 1994

PART IV

Advertising etc. to Health Professionals

Scope of Part IV

- 13.—(1) Subject to paragraph (2), this Part, with the exception of regulations 19, 20 and 21, applies only to advertisements wholly or mainly directed at persons qualified to prescribe or supply relevant medicinal products, and accordingly references in this Part to advertisements are to advertisements to which this Part applies.
 - (2) Nothing in this Part has any effect in relation to veterinary surgeons or veterinary practitioners.

Advertisements to health professionals

14.—(1) Subject to paragraph (2)

and to regulations 17 and 22(2), no person shall issue an advertisement relating to a relevant medicinal product unless such advertisement—

- (a) contains essential information compatible with the summary of product characteristics,
- (b) contains the particulars set out in paragraphs 1 to 9 of Schedule 2, and
- (c) is in accordance with paragraph 10 of Schedule 2.
- (2) This regulation shall not apply to an advertisement to which regulation 15 or 16 applies.

Audio-visual advertisements

- **15.**—(1) Subject to regulations 17 and 22(2), no person shall issue in a programme service or video recording any advertisement relating to a relevant medicinal product which includes or shows any words, unless that advertisement—
 - (a) contains essential information compatible with the summary of product characteristics, and
 - (b) refers to the particulars contained in paragraphs 1 to 8 of Schedule 2.
- (2) For the purposes of this regulation the particulars contained in Schedule 2 may (where appropriate) be supplied by way of written material made available to all persons to whom the advertisement is shown or sent as an alternative to being referred to in the advertisement.
- (3) In this regulation, "programme service" has the meaning assigned to it in section 201 of the Broadcasting Act 1990(1).

⁽¹⁾ Contravention of regulation 12 is an offence by virtue of section 67(2) of the Act, for which the penalties specified in section 67(4) apply.

Abbreviated advertisements

- **16.** Subject to regulations 17 and 22(2), no person shall issue an abbreviated advertisement relating to a relevant medicinal product unless such advertisement—
 - (a) contains essential information compatible with the summary of product characteristics;
 - (b) contains the particulars set out in Schedule 3,

and any warning which the licensing authority has required in exercise of powers under Part II of the Act to be included in any advertisement relating to that medicinal product has been included.

Exception for promotional aids

- **17.** The prohibitions and requirements imposed by regulations 14, 15 and 16 shall not apply to an advertisement relating to a relevant medicinal product which is on a promotional aid if—
 - (a) the advertisement consists solely of the name of the product (or, in the case of a registered homoeopathicmedicinal product, the scientific name of the stock or stocks); and
 - (b) the advertisement is intended solely as a reminder.

Written material accompanying promotions

- **18.**—(1) No person shall send or deliver to persons qualified to prescribe or supply relevant medicinal products as part of the promotion of a relevant medicinal product any written material relating to that product unless it—
 - (a) includes essential information compatible with the summary of product characteristics,
 - (b) contains the particulars specified in paragraph 3 of Schedule 2, and
 - (c) states the date on which it was drawn up or last revised.
- (2) No person shall include any information in written material to which paragraph (1) applies which is not accurate, up-to-date, verifiable or sufficiently complete to enable the recipient to form his own opinion of the therapeutic value of the product to which the documentation relates.
- (3) No person shall include in written material to which paragraph (1) applies any quotation, table or other illustrative matter taken from a medical journal or other scientific work unless it is accurately reproduced and the precise sources of the information indicated.

Free samples

- 19.—(1) This regulation applies only to the supply of a free sample of a relevant medicinal product to a person who receives it for the purpose of acquiring experience in dealing with such a product.
 - (2) A person may supply a sample to which this regulation applies only—
 - (a) to a person qualified to prescribe relevant medicinal products,
 - (b) if the sample is of a medicinal product which does not contain—
 - (i) a substance which is listed in any of Schedules I, II or IV to the Narcotic Drugs Convention (where the product is not a preparation listed in ScheduleIII to that Convention), or
 - (ii) a substance which is listed in any of Schedules I to IV of the Psychotropic Substances Convention (where the product is not a preparation which may be exempted from measures of control in accordance with paragraphs 2 and 3 of article 3 of that Convention),

and

(c) in accordance with Schedule 4.

Medical sales representatives

- **20.**—(1) This regulation applies only to the activities of medical sales representatives who promote relevant medicinal products to persons qualified to prescribe such products.
- (2) In relation to any relevant medicinal product which they promote, all medical sales representatives shall, during each visit, give to all persons whom they visit or have available for them a copy of the summary of product characteristics (or, if there is no summary of product characteristics, a copy of the data sheet) for each such product.
- (3) In relation to the use of any relevant medicinal product which they promote, all medical sales representatives shall forthwith report all information which they receive from persons whom they visit, including reports of any adverse reactions, to the scientific service established in accordance with regulation 4(a).

Inducements and hospitality

- 21.—(1) Subject to paragraphs (2)
- and (4), where relevant medicinal products are being promoted to persons qualified to prescribe or supply relevant medicinal products, no person shall supply, offer or promise to such persons any gift, pecuniary advantage or benefit in kind, unless it is inexpensive and relevant to the practice of medicine or pharmacy.
 - (2) The provisions of paragraph (1)
- shall not prevent any person offering hospitality (including the payment of travelling or accommodation expenses) at events for purely professional or scientific purposes to persons qualified to prescribe or supply relevant medicinal products, provided that—
 - (a) such hospitality is reasonable in level,
 - (b) it is subordinate to the main scientific objective of the meeting and
 - (c) it is offered only to health professionals.
- (3) Subject to paragraph (4), no person shall offer hospitality (including the payment of travelling or accommodation expenses) at a meeting or event held for the promotion of relevant medicinal products unless—
 - (a) such hospitality is reasonable in level,
 - (b) it is subordinate to the main purpose of the meeting or event, and
 - (c) the person to whom it is offered is a health professional.
- (4) Nothing in this regulation shall affect measures or trade practices relating to prices, margins or discounts which were in existence on 1st January 1993.
- (5) No person qualified to prescribe or supply relevant medicinal products shall solicit or accept any gift, pecuniary advantage, benefit in kind, hospitality or sponsorship prohibited by this regulation.