STATUTORY INSTRUMENTS

1994 No. 1932

MEDICINES

The Medicines (Advertising) Regulations 1994

Made - - - -	*18th July 1994*
Laid before Parliament	*19th July 1994*
Coming into force - -	*9th August 1994*

The Secretary of State, 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 section 2(2) of the Act in relation to medicinal products(**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 powers conferred upon them by sections 61, 66(1)(i) and (j), 95(1), (2), (3), (4), (5) and (6) and 129(5) of the Medicines Act 1968(**3**), or, as the case may be, those conferred by the said provisions and now vested in them(**4**), and those Ministers together with the Minister of Agriculture, Fisheries and Food, the Secretaries of State respectively concerned with agriculture in Scotland and in Wales and the Department of Agriculture for Northern Ireland, acting jointly in exercise of the powers conferred upon them by sections 85(1), 86(1) and 91(2) of the Medicines Act 1968(**5**), or, as the case may be, those conferred by the said provisions and now vested in them(**6**), and in each case in exercise of all other powers so enabling them, after consulting in so far as is required such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations(**7**), hereby make the following Regulations:

(**1**) 1972 c. 68.
(**2**) S.I.1972/1811.
(**3**) 1968 c. 67. The expression "the appropriate Ministers", used in sections 61, 66 and 95, is defined in section 1(2)(a) of that Act.
(**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 (S.I. 1969/388) 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**) The expression "the appropriate Ministers", used in sections 85 and 86, is defined in section 1(2)(b) of that Act.
(**6**) In the case of the Secretary of State concerned with agriculture in Wales by virtue of article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272) and in the case of the Department of Agriculture 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).
(**7**) *See* section 129(6) of the Act.

PART I

GENERAL

Citation and commencement

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

Interpretation

2.—(1) In these Regulations—

"the Act" means the Medicines Act 1968;

"abbreviated advertisement" means an advertisement, other than a loose insert, which does not exceed in size an area of 420 square centimetres, in a publication sent or delivered wholly or mainly to persons qualified to prescribe or supply relevant medicinal products;

"common name" in relation to a relevant medicinal product means the international non-proprietary name, or, if one does not exist, the usual common name;

"essential information compatible with the summary of product characteristics" means essential information compatible—

(a) with the summary of product characteristics, if there is one, or

(b) if there is no summary of product characteristics, with the data sheet,

and "essential information" has the meaning it bears in Council Directive 92/28/EEC(**8**);

"medicinal product for supply by prescription only" means a medicinal product of a description or falling within a class specified in any order made under section 58 of the Act(**9**);

"medicinal product on a general sale list" means a medicinal product of a description or falling within a class specified in any order made under section 51(1) of the Act;

"name" in relation to a relevant medicinal product means the name given to the product which may be either an invented name or a common or scientific name, together with a trade mark or the name of the person responsible for marketing the product;

"pharmacy medicinal product" means a medicinal product which is neither a medicinal product for supply by prescription only nor a medicinal product on a general sale list;

"promotional aid" means a non-monetary gift made for a promotional purpose by a commercially interested party;

"reference material" includes entries which are in the form of, and limited to, a brief description of a medicinal product, its uses and any relevant contra-indications and warnings, appearing without charge in a publication consisting wholly or mainly of such entries where the publication is sent or delivered to persons qualified to prescribe or supply relevant medicinal products by a person who is not a commercially interested party;

"registered homoeopathic medicinal product" means a homoeopathic medicinal product(**10**)to which Council Directive 92/73/EEC(**11**)applies which is marketed in the United Kingdom under a certificate of registration(**12**)in accordance with the provisions of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**13**);

(**8**) OJ No. L113, 30.4.1992, p.13.
(**9**) Section 58 was amended by the Medicinal Products: Prescription by Nurses etc Act 1992 (c. 28), as from a day to be appointed.
(**10**) The definition of homoeopathic medicinal product was inserted into section 7 of the Act by regulation 3(4) of S.I. 1994/276.
(**11**) OJ No. L297, 13.10.1992, p.8.
(**12**) The definition of certificate of registration was inserted into section 7 of the Act by regulation 3(4) of S.I. 1994/276.
(**13**) S.I. 1994/105, amended by S.I. 1994/899.

"relevant medicinal product" means—

(a) a medicinal product for human use to which Chapters II to V of the 1965 Directive(**14**)apply,

(b) a substance or article for human use—

(i) to which Chapters II to V of the 1965 Directive apply, and

(ii) specified in an order made under section 104 or 105 of the 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 Act has effect in relation to such substance or article as that Part or section has effect in relation to medicinal products within the meaning of the Act, or

(c) a registered homoeopathic medicinal product,

but does not include a homoeopathic medicinal product in respect of which there is in force a product licence being a licence of right;

"summary of product characteristics" means the information required to accompany any application for a product licence by virtue of article 4a of the 1965 Directive which was inserted by article 1(2) of Council Directive 83/570/EEC(**15**)and amended by article 1(1) and (4) of Council Directive 89/341/EEC(**16**);

and expressions used in these Regulations which are used in any provision of the Act have, subject to paragraph (2) and unless the context requires otherwise, the meaning which they bear in the Act.

(2) For the purposes of these Regulations, "advertisement" has the meaning assigned to it by section 92 of the Act, except that, in relation to a relevant medicinal product—

(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 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, unless the context requires otherwise, a reference to a regulation, Part or Schedule is to that regulation in, Part of or Schedule to, these Regulations and any reference in a regulation or Schedule to a numbered paragraph is to the paragraph of that regulation or Schedule bearing that number.

PART II

Advertising—General

Prohibition of advertisements for unlicensed products

3.—(1) Subject to paragraph (2), no person shall issue an advertisement relating to a relevant medicinal product in respect of which no product licence is in force.

(2) This regulation shall not apply to any advertisement relating to a registered homoeopathic medicinal product.

(**14**) The definition of the 1965 Directive in section 132(1) of the Act was amended by regulation 9 of S.I. 1994/276.
(**15**) OJ No. L332, 28.11.1983, p.1.
(**16**) OJ No. L142, 25.5.1989, p.11.

Duties of licence holders

4. Any person who holds a product licence relating to a relevant medicinal product shall—

(a) establish a scientific service to compile and collate all information, whether received from medical sales representatives employed by him or from any other source, relating to that product;

(b) ensure that, in relation to any such product which medical sales representatives promote, those medical sales representatives are given adequate training and have sufficient scientific knowledge to enable them to provide information which is as precise and as complete as possible about that product;

(c) whenever required to do so by the licensing authority, furnish particulars of any advertisement or proposed advertisement for which he is responsible relating to that product, including particulars as to the contents and form of the advertisement, the method of dissemination and the date of first dissemination; and

(d) ensure that, in relation to an advertisement relating to that product, any decision taken by the licensing authority is immediately and fully complied with.

PART III

Advertising to the Public

Scope of Part III

5. This Part, with the exception of regulation 12 (prohibition of supply of medicinal products to the public), applies only to advertisements wholly or mainly directed at members of the general public, and accordingly references in this Part to advertisements are to advertisements to which this Part applies.

Prohibition of advertisements referring to specified diseases

6.—(1) Subject to paragraph (2)

and to regulation 11, no person shall issue an advertisement which is likely to lead to the use of a relevant medicinal product for the purpose of the treatment, prevention or diagnosis of any disease specified in, or any disease falling within a class of disease specified in, Schedule 1.

(2) Paragraph (1) shall not be taken to prohibit a person from issuing an advertisement which is likely to lead to the use of a relevant medicinal product for the purpose of the prevention of neural tube defects.

(3) No person shall issue an advertisement which is likely to lead to the use of a relevant medicinal product or any other medicinal product, substance or article for the purpose of inducing an abortion in women.

Prohibition of advertisements for medicinal products on prescription only

7. Subject to regulation 11, no person shall issue an advertisement which is likely to lead to the use of a relevant medicinal product which is a medicinal product for supply by prescription only and which is subject to any of the restrictions imposed by section 58(2) of the Act.

Prohibition of advertisements relating to certain medicinal products

8. Subject to regulation 11, no person shall issue an advertisement relating to any relevant medicinal product which—

(a) contains a substance which is listed in any of Schedules I, II or IV to the Narcotic Drugs Convention(**17**)(where the product is not a preparation listed in Schedule III to that Convention); or

(b) contains a substance which is listed in any of Schedules I to IV of the Psychotropic Substances Convention(**18**)(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).

Prohibition of certain material in advertisements

9.—(1) Subject to regulation 11, no person shall issue an advertisement relating to any relevant medicinal product which contains any material which—

(a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by post, FAX or telephone,

(b) suggests that the effects of taking the medicinal product are guaranteed, are unaccompanied by side effects or are better than, or equivalent to, those of another identifiable treatment or medicinal product,

(c) suggests that health can be enhanced by taking the medicinal product,

(d) suggests that health could be affected by not taking the medicinal product,

(e) is directed exclusively or principally at children,

(f) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products,

(g) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product,

(h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural,

(i) might, by a description or detailed representation of a case history, lead to erroneous self-diagnosis,

(j) refers, in improper, alarming or misleading terms, to claims of recovery,

(k) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof, or

(l) mentions that the medicinal product has been granted a product licence.

(2) In this regulation, "FAX" means the making of a facsimile copy of a document by the transmission of electronic signals.

Form and content of advertisements

10.—(1) Subject to paragraph (2), no person shal issue an advertisement relating to a relevant medicinal product unless that advertisement—

(a) is set out in such a way that it is clear that the message is an advertisement and so that the product is clearly identified as a medicinal product, and

(b) subject to regulation 22(2), includes the following—

(i) the name of the medicinal product,

(**17**) The Narcotic Drugs Convention and the Psychotropic Substances Convention are defined in section 58A(5) of the Act. Section 58A was inserted into the Act by S.I. 1992/3271.
(**18**) 1990 c. 42.

(ii) if it contains only one active ingredient, the common name of the medicinal product,

(iii) the information necessary for correct use of the medicinal product, and

(iv) an express and legible invitation to read carefully the instructions on the leaflet contained within the package or on the label, as the case may be.

(2) This regulation 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 homoeopathic medicinal product, the scientific name of the stock or stocks), and

(b) the advertisement is intended solely as a reminder.

Exception for approved vaccination campaigns

11. The provisions of regulations 6(1), 7, 8 and 9(1)(d) shall not apply to any advertisement as part of a vaccination campaign relating to a relevant medicinal product which is a vaccine or serum, provided that such campaign has been approved by the Health Ministers.

Prohibition of supply of medicinal products to the public

12. No person—

(a) being the holder of a product licence; or

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

shall sell or supply for a promotional purpose any unsolicited relevant medicinal product to any member of the general public.

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 section201 of the Broadcasting Act 1990(**19**).

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.

(**19**) 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.

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.

PART V

Registered Homoeopathic Medicinal Products

Advertisements for registered homoeopathic medicinal products

22.—(1) No person shall issue an advertisement relating to a registered homoeopathic medicinal product which—

(a) contains any details which are not specified in Schedule 5; or

(b) mentions any specific therapeutic indications.

(2) Nothing in regulations 10(1)(b), 14(1), 15(1)

or 16 shall be construed as requiring in an advertisement relating to a registered homoeopathic medicinal product the inclusion of any detail which is not specified in Schedule 5.

PART VI

Offences

Offences

23.—(1) Any person who contravenes regulations 3(1), 4, 6(1)

or (3), 7, 8, 10(1), 14(1), 15(1), 16, 18(1), (2) or (3), 20(2) or (3), 21(1) or (3), or 22(1)(a)shall be guilty of an offence and shall be liable—

(a) on summary conviction, to a fine not exceeding the statutory maximum,

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

(2) Any person who contravenes regulation 19 or 21(5)

shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

PART VII

Revocations, Amendments and Transitional Provision

Revocations and amendments

24.—(1) The Medicines (Advertising to Medical and Dental Practitioners)

Regulations 1978(**20**)are revoked.

(2) Paragraph (2)

of regulation 2 of the Medicines (Advertising of Medicinal Products) (No. 2) Regulations 1975(**21**)is revoked.

(3) After regulation 1 of the Medicines (Labelling and Advertising to the Public) Regulations 1978(**22**)there is inserted—

"**Application of these regulations**

1A. These regulations do not apply to any advertisement or representation relating to a relevant medicinal product as defined by regulation 2(1) of the Medicines (Advertising) Regulations 1994(**23**).".

Transitional provision

25. The provisions of Parts III and IV shall not have effect in relation to any advertisement relating to a relevant medicinal product in respect of which advertisement a contract has been made before the coming into force of these Regulations under the terms of which that advertisement may not be cancelled or altered without a financial penalty being payable.

Signed by authority of the Secretary of State for Health.

Department of Health
18th July 1994

Tom Sackville
Parliamentary Under Secretary of State

John Redwood
11th July 1994
Secretary of State for Wales

The Scottish Office
15th July 1994

Fraser of Carmyllie

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 14th July 1994.

Gillian Shephard
Minister of Agriculture, Fisheries and Food

(**20**) S.I. 1978/1020.
(**21**) S.I. 1975/1326.
(**22**) S.I. 1978/41.
(**23**) S.I. 1994/1932.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 18th July 1994.

F. A. Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 18th July 1994.

J. Murray
Permanent Secretary

SCHEDULE 1

Regulation 6

Diseases in Respect of which Advertisements to the Public are Prohibited

Bone diseases

Cardiovascular diseases

Chronic insomnia

Diabetes and other metabolic diseases

Diseases of the liver, biliary system and pancreas

Endocrine diseases

Genetic disorders

Malignant diseases

Psychiatric diseases

Serious disorders of the eye and ear

Serious gastrointestinal diseases

Serious infectious diseases including HIV-related diseases and tuberculosis

Serious neurological and muscular diseases

Serious renal diseases

Serious respiratory diseases

Serious skin disorders

Sexually transmitted diseases.

SCHEDULE 2

Regulations 14 and 15

Particulars to be Contained in Advertisements to Health Professionals

1. The licence number of the medicinal product.

2. The name and address of the holder of the product licence which relates to the medicinal product or the business name and address of the part of his business that is responsible for its sale or supply.

3. The supply classification of the medicinal product, specifying whether the product is a medicinal product for supply by prescription only, a medicinal product on a general sale list, or a pharmacy medicinal product.

4. The name of the product, and a list of the active ingredients using the common name placed immediately adjacent to the most prominent display of the name of the product.

5. One or more of the indications for the product consistent with the terms of the licence.

6. A succinct statement (where relevant) of the entries in the summary of product characteristics or, if there is no summary of product characteristics, the data sheet, relating to side-effects, precautions and relevant contra-indications.

7. A succinct statement of the entries in the summary of product characteristics or, if there is no summary of product characteristics, the data sheet, relating to dosage and method of use relevant to the indications shwn. The method of administration should also be shown where this is not obvious.

8. A warning issued by the licensing authority under Part II of the Act which is required to be included in advertisements.

9. The cost (excluding value added tax) of either a specified package of the medicinal product to which the advertisement relates, or a specified quantity or recommended daily dose, calculated by reference to any specified package of the product, except that such cost may be omitted in the case of an advertisement inserted in a publication which is printed in the United Kingdom but with a circulation outside the United Kingdom of more than 15 per cent. of its total circulation.

10. The particulars contained in paragraphs 6, 7 and 8 shall be printed in a clear and legible manner and be placed in such a position in the advertisement that their relationship to the claims and indications for the product can readily be appreciated by the reader.

SCHEDULE 3

Regulation 16

Particulars to be Contained in Abbreviated Advertisements

1. The name and address of the holder of the product licence which relates to the medicinal product, or the business name and address of the part of his business that is responsible for its sale or supply.

2. The supply classification of the medicinal product, specifying whether the product is a medicinal product for supply by prescription only, a medicinal product on a general sale list, or a pharmacy medicinal product.

3. The name of the product, and a list of the active ingredients using the common name placed immediately adjacent to the most prominent display of the name of the product.

4. A form of words which clearly indicates that further information is available on request to the licence holder or in the summary of product characteristics, or, if there is no summary of product characteristics, the data sheet, relating to the product.

SCHEDULE 4

Regulation 19

Conditions for the Supply of Free Samples

1. Samples shall be supplied on an exceptional basis only.

2. A limited number only of samples of each product may be suppied in any one year and to any one recipient.

3. Samples shall be supplied only in response to a written request, signed and dated, from the recipient.

4. Suppliers of samples shall maintain an adequate system of control and accountability.

5. Every sample shall be no larger than the smallest presentation available for sale in the United Kingdom.

6. Every sample shall be marked “free medical sample—not for resale” or shall bear a similar description.

7. Every sample shall be accompanied by 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.

SCHEDULE 5

Regulation 22

Particulars which may be Contained in Advertisements for Registered Homoeopathic Medicinal Products

1. The scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used in relation to the homoeopathic manufacturing procedure described therein for that stock or stocks.

2. The name and address of the holder of the certificate of registration and, where different, the name and address of the manufacturer.

3. The method of administration and, if necessary, route.

4. The expiry date of the product in clear terms (stating the month and year).

5. The pharmaceutical form.

6. The contents of the sales presentation.

7. Any special storage precautions.

8. Any special warning necessary for the product concerned.

9. The manufacturers batch number.

10. The registration number allocated by the licensing authority preceded by the letters "HR" in capital letters.

11. The words "homoeopathic medicinal product without approved therapeutic indications".

12. A warning advising the user to consult a doctor if the symptoms persist during the use of the product.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, made under powers contained in the Medicines Act 1968 and in the European Communities Act 1972, implement parts of Council Directive 92/28/EEC (OJ No. L113, 0.4.1992, p.13) ("the Advertising Directive") concerning the advertising of medicinal products for human use and parts of Council Directive 92/73/EEC (OJ No. L297, 13.10.1992, p.8) ("the Homoeopathics Directive") concerning homoeopathic medicinal products for human use. The Regulations relate only to medicinal products for human use: see the definition of "relevant medicinal product" in regulation 2(1).

The Regulations cover homoeopathic products marketed under a certificate of registration, implementing article 6(3) of the Homoeopathics Directive, but not those marketed under a product licence of right.

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 Advertising Directive, and includes a representation (regulation 2(2)).

Regulation 3 creates the new offence of advertising a medicinal product in respect of which there is no product licence (except a homoeopathic product marketed under a certificate of registration).

Regulation 4 places the holder of a product licence under a duty to monitor information received about products which he promotes, provide adequate training for medical sales representatives, provide particulars of advertisements to the licensing authority on request and ensure that any decisions taken by the licensing authority regarding advertisements are complied with. These provisions implements articles 8(1) and 13 of the Advertising Directive.

Part III of the Regulations concerns advertising of medicinal products to the general public. Regulation 6 prohibits advertisements for medicinal products for the treatment, prevention or diagnosis of certain diseases specified in Schedule 1, implementing article 3(2) of the Advertising Directive. Article 3(1) of the Directive is implemented by regulations 7 (prohibition of advertisements for medicinal products on prescription only) and 8 (prohibition of advertisements relating to certain medicinal products). Regulation 9 implements article 5 of the Advertising Directive, prohibiting various forms of misleading advertisements, and regulation 10 implements article 4, specifying the form and content of advertisements (except in relation to name-only advertisements on promotional aids). Regulation 11 provides for an exemption from certain of the requirements of the Regulations for advertisements which are part of an approved vaccination campaign (article 3(4) of the Advertising Directive), and regulation 12 prohibits the supply of medicinal products to the general public (article 3(6) of that Directive).

Part IV of the Regulations concerns advertising of medicinal products to health professionals. Regulations 14 and 15 implement article 6(1) of the Advertising Directive, providing that advertisements to health professionals, including audio-visual advertisements, shall contain essential information compatible with the summary of product characteristics (see the definition in regulation 2(1)) together with the particulars specified in Schedule 2. Regulation 16 applies the requirements of article 6(1) also to abbreviated advertisements, which must include the particulars specified in Schedule 3 to the Regulations. The provisions of regulations 14, 15 and 16 do not apply to name-only advertisements on promotional aids (regulation 17).

Article 7 of the Advertising Directive (requirements for written material accompanying promotions) is implemented by regulation 18. Implementing article 11 of the Advertising Directive, regulation 19 and Schedule 4 regulate the provision of free samples to persons qualified to prescribe medicinal products.

Regulation 20 regulates the promotion of medicinal products by medical sales representatives and implements article8(2) and (3) of the Advertising Directive. Regulation 21 regulates the provision of inducements and hospitality in relation to medicinal products, implementing articles 9 and 10 of that Directive.

Regulation 22 and Schedule 5 implement articles 6(3) (second indent) and 7(2) of the Homoeopathics Directive, specifying the particulars which advertisements for homoeopathic medicinal products marketed under a certificate of registration may contain.

Regulation 23 provides that breach of any of the provisions of the Regulations there specified is a criminal offence, and specifies penalties.

Part VII deals with revocations, amendments and transitional provisions. The Medicines (Advertising to Medical and Dental Practitioners) Regulations 1978 are revoked, and the Medicines (Labelling and Advertising to the Public) Regulations 1978 are amended so that those Regulations do not apply to an advertisement or representation for a medicinal product covered by these Regulations (regulation 24).

Regulation 25 contains a transitional provision exempting from the requirements of Parts III and IV of the Regulations advertisements for which a contract has already been made and which cannot be altered without incurring a financial penalty.

Implementation of the Advertising Directive is completed by the Medicines (Monitoring of Advertising) Regulations 1994, which implement article 12 (monitoring of advertising). Implementation of the remaining articles of the Homoeopathics Directive is completed by four sets of Regulations: the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, the Medicines Act 1968 (Amendment) (No. 2) Regulations 1994, the Medicines (Labelling and Leaflets) Amendment Regulations 1994, and the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1994.