STATUTORY INSTRUMENTS

1978 No. 1020

MEDICINES

The Medicines (Advertising to Medical and Dental Practitioners) Regulations 1978

Made - - - -	17*th July* 1978
Laid before Parliament	25*th July* 1978
Coming into Operation	1*st December* 1978

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 by sections 95 and 129(5) of the Medicines Act 1968(a) and now vested in them(b) and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by the following regulations and after consulting and taking into account the advice of the Medicines Commission, hereby make the following regulations:—

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines (Advertising to Medical and Dental Practitioners) Regulations 1978 and shall come into operation on 1st December 1978.

(2) In these regulations—

"abbreviated advertisement" means an advertisement, other than a loose insert, in a professional publication which complies with the requirements imposed by regulation 5(*d*) of, and Schedule 2 to, these regulations;

"the Act" means the Medicines Act 1968;

"advertisement" has the same meaning as in section 92(1) and (2) of the Act but these regulations shall only apply to advertisements which are issued for the purpose of inducing a doctor or dentist to prescribe, supply, administer or procure the administration of medicinal products of a particular description;

"approved name" means the name which appears in the current edition (as defined in section 103(5) of the Act) of the list prepared and published under section 100 of the Act as in force at the time of the issue of the advertisement;

(a) 1968 c. 67.

(b) 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 1975 (c. 28).

"approved synonym" has the meaning assigned by section 65(8) of the Act;

"commercially interested party" has the same meaning as in section 92(4) of the Act;

"data sheet" has the meaning assigned to it in section 96(6) of the Act;

"multi-page advertisement" means an advertisement inserted on two or more consecutive pages of a professional publication;

"promotional aid" means a non-monetary gift made to a doctor or dentist for promotional purposes by or on behalf of a holder of a licence under Part II of the Act;

"professional publication" means a publication sent or delivered wholly or mainly to doctors or dentists containing an advertisement to which these regulations apply;

"reference advertisement" means an advertisement which is in the form of, and limited to, a brief description of a medicinal product, its uses and any contra-indications and warnings relevant thereto appearing without charge in a publication consisting wholly or mainly of such advertisements where the publication is sent or delivered to practitioners or pharmacists by a person who is not a commercially interested party;

"the specified particulars" means the particulars required by regulations 2(1) and 3(1) of, and Schedule 1 to, these regulations;

"specified publication" has the meaning assigned by section 103(1) of the Act;

"trade advertisement" means an advertisement relating to a medicinal product issued by means of a catalogue, price list or other document for the purpose of the sale (whether by the person who manufactures it or otherwise) of that medicinal product to persons who buy such a product for one or more of the purposes specified in section 131(2) of the Act where such catalogue, price list or document does not contain any recommendation relating to the use of the medicinal product other than as part of the name of the medicinal product or as part of any heading or sub-heading indicating a therapeutic classification;

and other expressions have the same meaning as in the Act.

(3) Except in so far as the context otherwise requires, any reference in these regulations to any provision of any enactment shall be construed as a reference to that provision as amended or extended by any enactment or instrument and as including a reference to any provision which may re-enact or replace it.

(4) The rules for the construction of Acts of Parliament contained in the Interpretation Act 1889(a) shall apply for the purpose of the interpretation of these regulations as they apply for the purposes of an Act of Parliament.

(a) 1889 c. 63.

Certain advertisements in professional publications

2.—(1) Subject to the following provisions of these regulations every advertisement or page of an advertisement (other than a data sheet) of a kind described in paragraph (2) below relating to any medicinal product of a particular description which is for use by being administered to human beings shall comply with the requirements set out in Schedule 1 to these regulations.

(2) The kinds of advertisements to which this regulation applies are those contained in a professional publication at the request or with the consent of a commercially interested party.

Other advertisements addressed to practitioners

3.—(1) Subject to the following provisions of these regulations no advertisement or page of an advertisement (other than a data sheet) of a kind described in paragraph (2) below shall be issued relating to any medicinal product of a particular description which is for use by being administered to human beings unless such advertisement or page of an advertisement contains the particulars set out in, and complies with the form required by, Schedule 1 to these regulations.

(2) The kinds of advertisements to which this regulation applies are those addressed to a doctor or dentist other than those advertisements described in regulation 2(2) above.

Audio-visual advertisements

4.—(1) Subject to the provisions of these regulations no advertisement addressed to a doctor or dentist relating to a medicinal product which is for use by being administered to human beings shall be issued which includes—

(*a*) words forming part of a sound recording or embodied in a sound-track associated with a cinematograph film;

(*b*) words broadcast by way of sound broadcasting or television or transmitted to subscribers to a diffusion service;

(*c*) words shown as part of a cinematograph film or television broadcast;

unless it complies with regulations 8 and 9 of these regulations and refers to the particulars contained in paragraphs 5, 6 and 7 of Schedule 1 to these regulations.

(2) For the purposes of this regulation the particulars contained in paragraphs 5, 6 and 7 of the said Schedule 1 may (where appropriate) be supplied by way of written material handed to an audience as an alternative to being referred to in the advertisement.

Exceptions for certain advertisements

5. The prohibitions and requirements imposed by regulations 2, 3 and 4 above shall not apply to the following—

(*a*) trade advertisements;

(*b*) written notices of changes in packaging, warnings of adverse reactions or notices of defective medicinal products if no medical claims for such products are made in such notices;

(*c*) reference advertisements if—

(i) the publication in which the advertisement appears contains an index listing in alphabetical order all the non-proprietary names of all the active ingredients of the products for which reference advertisements are shown;

(ii) a data sheet has been prepared for each medicinal product in respect of which a reference advertisement is shown in that publication, and that three copies of such data sheet have been sent or delivered to the licensing authority on or after the date upon which these regulations came into operation, except where a data sheet is not required by section 96(1) of the Act and the licensing authority are satisfied that there is small use of the said product;

(iii) the publication in which the advertisement appears contains a notice stating that data sheets are (where relevant) available on request for all medicinal products for which reference advertisements are included except in those cases where the holder of the product licence has taken all reasonable steps, prior to arranging for the issue of the advertisement in question, to ensure that a data sheet relating to medicinal products of that description has been sent or delivered to any doctor or dentist to whose attention the holder of such product licence might reasonably expect the advertisement to come and whom the holder of such product licence might reasonably expect to prescribe, supply or administer such product;

(iv) the publication in which the advertisement appears contains a list of the names and addresses of the holders of the product licences for all the medicinal products for which reference advertisements are included; and

(v) the holder of the product licence has not objected to the issue of such an advertisement on the ground that a direction in writing given by the licensing authority under paragraph 11 of Part I of Schedule 1 to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**a**), as amended(**b**), requires that specified information be included in advertisements for the medicinal product to which the advertisement relates or requires that warnings as to the effect of such product should be included in a manner specified in such direction.

(*d*) abbreviated advertisements if—

(i) such advertisements contain the particulars set out in, and comply with the form required by, Schedule 2 to these regulations;

(ii) the Commission, the appropriate committee or the licensing authority have not required a warning to be included in any advertisement relating to that medicinal product and the licensing authority have not issued a direction that abbreviated advertisements should not be issued;

(*e*) multi-page advertisements;

(*f*) any advertisement where the holder of the product licence which relates to the medicinal product has sent or delivered a copy of the

(**a**) S.I. 1971/972.
(**b**) The relevant amending instrument is S.I. 1974/1523.

advertisement to the licensing authority and such authority have not, within the period of 42 days commencing with the date of receipt of the advertisement by the said authority, notified the holder of the product licence that the advertisement should not be issued; or

(*g*) any letter written to a doctor or dentist in reply to a specific enquiry or comment made by or on behalf of such person in relation to a medicinal product of a particular description.

Exceptions for promotional aids

6. The prohibitions and requirements imposed by regulations 2, 3 and 4 above shall not apply to advertising on promotional aids if such advertising consists only of one or more of the following particulars, namely—

(*a*) the name of a particular medicinal product;

(*b*) the name of the holder of the relevant product licence or the business name of that part of his business responsible for the sale or supply of the medicinal product;

(*c*) the address of the holder of the relevant product licence or the address of that part of his business responsible for the sale or supply of the medicinal product;

(*d*) where the name of the product is a trade mark, an indication that such a name is a trade mark.

Exceptions for other advertising material

7. The prohibitions and requirements imposed by regulations 2, 3 and 4 above shall not apply to any advertisement relating to a medicinal product which is for use by being administered to human beings which is sent through the post or otherwise issued to a doctor or dentist if—

(*a*) the specified particulars are contained on at least one or more continuous pages of such advertisement; and

(*b*) in the case of such an advertisement which consists of more than four pages, it contains a clear statement of where the specified particulars may be found.

Prohibition of certain words and phrases

8. No advertisement addressed to a doctor or dentist shall be issued relating to any medicinal product which is for use by being administered to human beings which contains—

(*a*) a claim or suggestion that a medicinal product is better, more efficacious, safer, has fewer or less incidence of or less serious side-effects or contra-indications, unless such claim or suggestion accurately and clearly reflects available material evidence or can be substantiated by clinical experience, whether or not such claim or suggestion is made by comparison with another medicinal product or treatment, and whether or not such a claim or suggestion is made directly or through the use of published or unpublished literature, quotations or other references;

(*b*) the word 'safe' without qualification;

(*c*) any references to the Commission, the appropriate committee or the licensing authority unless this is specifically required by the licensing authority;

(*d*) any claim that the product is new unless it has been generally available in the United Kingdom for a period of less than one year from the date of issue of the advertisement; or

(*e*) any claim that a therapeutic indication is new after the period of one year from the date of the first advertisement for the said product which includes a reference to such new therapeutic indication.

Requirements for graphs and tables

9. Any graph or table contained in or forming part of any advertisement addressed to a doctor or dentist relating to a medicinal product which is for use by being administered to human beings shall—

(*a*) give a true and fair view of the matters with which it deals; and

(*b*) be relevant to any claim made in that advertisement in relation to that product.

Multi-page advertisements

10.—(1) No multi-page advertisement addressed to a doctor or dentist shall be issued relating to any medicinal product which is for use by being administered to human beings—

(*a*) if any double-page spread, or first (initial recto), or last (final verso) page is false or misleading if read in isolation;

(*b*) unless the specified particulars are contained on at least one of the pages of such an advertisement; and

(*c*) unless each page of such an advertisement contains (except the page on which, or facing which, the specified particulars are printed) on an outer edge, in type of at least 8 point size, a reference which clearly shows on which page of the said advertisement the specified particulars are printed.

(2) In this regulation the expression "false or misleading" has the same meaning as in section 93(7) of the Act.

Transitional provisions

11. These Regulations shall not have effect—

(1) in relation to advertisements issued in a professional publication (other than such advertisements relating to medicinal products to which a licence is granted under Part II of the Act on or after the date upon which these regulations come into operation) until 1st March 1979 except that reference advertisements shall not be required to comply with the conditions set out in regulation 5(*c*)(ii) and (iii) until 1st July 1979;

(2) in relation to any advertisement consisting of four or more pages or advertising on promotional aids printed before the coming into operation of these regulations, and which are sent through the post or otherwise delivered to a doctor or dentist, until 1st October 1982;

(3) in relation to any other advertisement to which these regulations apply until 1st October 1979.

Offences

12.—(1) Subject to paragraph (2) below any person who contravenes these regulations shall be guilty of an offence and—

(*a*) shall be liable on summary conviction to a fine not exceeding £400; and

(*b*) shall be liable on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both.

(2) In relation to regulation 2 of these regulations only a commercially interested party shall be guilty of an offence in respect of a contravention of the said regulation 2.

David Ennals,
Secretary of State for Social Services.

7th July 1978.

John Morris,
Secretary of State for Wales.

14th July 1978.

Bruce Millan,
Secretary of State for Scotland.

17th July 1978.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 17th day of July 1978.

(L.S.)

N. Dugdale,
Permanent Secretary.

Regulations 2(1)
and 3(1)

SCHEDULE 1

Requirements for advertisements

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 the business that is responsible for its sale or supply.

3. A list of the active ingredients placed immediately below the most prominent display of the name of the product and in a type size which occupies a total area no less than that occupied by the most prominent display of the said name, or of 10 point bold, in accordance with the following requirements—

(*a*) where the medicinal product is described in a monograph in a specified publication the name at the head of that monograph or, in the case of the European Pharmacopoeia, an approved synonym or, where such name consists of two or more words, any name derived from a suitable inversion of such words which is permitted by that specified publication, or

(*b*) where the medicinal product is not described in a monograph in a specified publication, but the active ingredients are described in monographs in a specified publication, the names at the head of those monographs or, in the case of the European Pharmacopoeia, an approved synonym or, where such names consist of two or more words, any name derived from a suitable inversion of such words which is permitted by that specified publication, or

(*c*) where neither the medicinal product nor its active ingredients are described in a monograph in a specified publication but the active ingredients of that medicinal product have approved names, such approved names, or where there are no approved names, the approved International Non-proprietary names, or

(*d*) where neither the medicinal product nor its active ingredients are described in a monograph in a specified publication and the active ingredients of that medicinal product do not have approved names or approved International Non-proprietary names, but the medicinal product or its active ingredients are described in a foreign or international compendium of standards, the name at the head of such monograph together with letters and figures identifying the publication and the edition, or

(*e*) in any other case, the accepted scientific name or any other name descriptive of the true nature of the medicinal product or its active ingredients.

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

5. A succinct statement (where relevant) of the entries on the data sheet relating to side-effects, precautions and relevant contra-indications.

6. A succinct statement of the entries on the data sheet relating to dosage and method of use relevant to the indications shown. The method of administration should also be shown where this is not obvious.

7. A warning issued by the Commission, the appropriate committee or the licensing authority which is required to be included in advertisements.

8. 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 said 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.

9. The particulars contained in paragraphs 5, 6 and 7 above of this Schedule should 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.

Regulation 5(*d*)

SCHEDULE 2

Particulars to be contained in, and the form required by, abbreviated advertisements

1. An abbreviated advertisement shall not exceed in size an area of more than 420 square centimetres.

2. An abbreviated advertisement shall contain the following information but, subject to the provisions of paragraph 3 of this Schedule, shall contain no other information relating to the product—

(*a*) the name of the medicinal product, being either the appropriate non-proprietary name or a proprietary designation;

(*b*) a list of the active ingredients which complies with the requirements of paragraph 3 of Schedule 1 to these regulations except that in the case of an abbreviated advertisement which does not exceed an area of more than 200 square centimetres, and is contained in the same therapeutic section of a publication consisting wholly or mainly of reference advertisements as a reference advertisement for the same medicinal product, the requirements as to type size do not apply;

(*c*) 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;

(*d*) a form of words which clearly indicates that further information is available on request to the licence holder or in the data sheet relating to the product.

3. In addition to the information required by paragraph 2 of this Schedule, an abbreviated advertisement may also include a reference to one indication for the use of the medicinal product to which it relates, or two or more of such indications if they are related, together with a concise statement (consistent with the data sheet) as to why such product is recommended for such indication or indications.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations made under section 95 of the Medicines Act 1968 regulate advertisements directed to medical and dental practitioners for medicinal products administered to human beings.

They impose prohibitions and requirements as to the contents of such advertisements providing for prescribed information, including the name and address of the licence holder, a list of the active ingredients, contra-indications, warnings and precautions and (except in the case of a product advertised in a journal with an overseas circulation of over 15 per cent.) the cost of the product, to be shown on the advertisement.

The Regulations contain provisions dealing with prescribed requirements for graphs and tables, audio-visual advertisements and multi-page advertisements.

The Regulations also contain prohibitions for certain words and phrases, transitional provisions and criminal sanctions.

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