STATUTORY INSTRUMENTS

1975 No. 1326

MEDICINES

The Medicines (Advertising of Medicinal Products) (No. 2) Regulations 1975

Made - - - -	*6th August* 1975
Laid before Parliament	*15th August* 1975
Coming into Operation	*8th September* 1975

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 section 95(3) and (6) 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 taking into account the advice of the Committee on Safety of Medicines**(c)**, hereby make the following regulations:—

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines (Advertising of Medicinal Products) (No. 2) Regulations 1975 and shall come into operation on 8th September 1975.

(2) In these regulations, unless the context otherwise requires—

"the Act" means the Medicines Act 1968;

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

"medicinal product" includes any substance or article specified in the Medicines (Surgical Materials) Order 1971**(d)**, in the Medicines (Dental Filling Substances) Order 1975**(e)** or in any other order made under section 104 or 105 of the Act subsequent to the coming into force of these regulations by virtue of which section 96 of the Act has effect in relation to such substance or article as that section has effect in relation to medicinal products within the meaning of the Act;

"professional publication" means a publication sent or delivered wholly or mainly to doctors or dentists, a publication containing an advertisement relating to a medicinal product which may only lawfully be sold by retail

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(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; 1969 I, p. 1070), 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 paragraph 2(1)(b) of Schedule 1 to the Northern Ireland Act 1974 (c.28).

(c) S.I. 1970/1257 (1970 II, p. 4098). **(d)** S.I. 1971/1267 (1971 II, p. 3632).

(e) S.I. 1975/533 (1975 I, p. 1754).

or supplied in circumstances corresponding to retail sale in accordance with a prescription given by a practitioner, or a publication containing an advertisement relating to a medicinal product in respect of which a data sheet has been issued;

"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 relating 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;

"relevant practitioner" means a doctor, where the medicinal product is for use exclusively by or under the direction of a doctor, or a dentist, where the medicinal product is for use exclusively by or under the direction of a dentist, or a doctor or dentist, where the medicinal product is not for either exclusive use as aforesaid;

"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 product for one or more of the purposes specified in section 131(2) of the Act (wholesale) 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 meanings as in the Act, and as in Part VI of the Act.

(3) Except in so far as the context otherwise requires, any reference in these regulations to any provision of any enactment or instrument 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 purposes of the interpretation of these regulations as they apply for the purposes of the interpretation of an Act of Parliament.

Requirements for advertisements relating to medicinal products in professional publications

2.—(1) Subject to the following provisions of these regulations, every advertisement, other than a data sheet, reference advertisement or trade advertisement, relating to a medicinal product of a particular description, not being a veterinary drug, issued in a professional publication by a commercially interested party or by any person at the request or with the consent of a commercially interested party, shall comply with the following requirements, that is to say—

(*a*) in so far as the advertisement in question contains particulars in respect of the information contained in a data sheet relating to a medicinal product of that description such particulars shall not be inconsistent with the particulars contained in such data sheet, and

(*b*) the advertisement in question shall contain particulars, in a prominent form, to the effect that a data sheet relating to medicinal products of that

(a) 1889 c. 63.

description will be sent or delivered to any relevant practitioner on request in writing.

(2) The requirements imposed by paragraph (1) of this regulation shall not apply to an advertisement relating to a medicinal product in respect of which an exemption from the restrictions imposed by section 7 of the Act applies by virtue of the Medicines (Exemption from Licences) (Foods and Cosmetics) Order 1971**(a)** as amended **(b)** or to an advertisement relating to a medicinal product which may lawfully be sold by retail or supplied in circumstances corresponding to retail sale otherwise than in accordance with a prescription given by a practitioner where such advertisement, being an advertisement issued in a professional publication which is sold or supplied generally to persons who are not practitioners, is not for the purpose of inducing a practitioner to prescribe or supply medicinal products of that description.

(3) The requirements imposed by sub-paragraph (*b*) of paragraph (1) of this regulation shall not apply where the holder of the product licence relating to the medicinal product in question 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 relevant practitioner 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 medicinal product.

(4) The requirements imposed by paragraph (1) of this regulation shall not, in the case of the holder of the product licence relating to the medicinal product in question, be regarded as complied with if such holder of the product licence fails to comply with a request from a relevant practitioner made by virtue of such particulars as are referred to in sub-paragraph (*b*) of that paragraph or if such holder of the product licence has not sent or delivered to the licensing authority not more than 15 months before the issue of the advertisement in question 3 copies of a data sheet relating to medicinal products of that description.

Temporary provisions

3.—(1) The requirements imposed by regulation 2 of these regulations shall not apply during a period of 2 months from the grant of the product licence relating to the medicinal product to which the advertisement in question relates if—

(*a*) the holder of the product licence relating to such medicinal product has, prior to the issue of such advertisement, sent or delivered to the licensing authority a document relating to that medicinal product which, whilst not a data sheet, nevertheless complies with the requirements as to particulars prescribed under section 96(6) of the Act**(c)**, and

(*b*) such advertisement is not inconsistent with the particulars contained in such document as aforesaid.

(2) Without prejudice to the provisions of paragraph (1) of this regulation, the requirements imposed by regulation 2 of these regulations shall not apply to the issue of any advertisement before 1st December 1975 if the arrangements for such issue were made before 1st October 1975.

(a) S.I. 1971/1410 (1971 II, p. 3945). **(b)** S.I. 1973/2079 (1973 III, p. 7182).
(c) *See* S.I. 1972/2076 (1972 III, p. 6155).

(3) Without prejudice to the provisions of paragraphs (1) or (2) of this regulation, in the case of a medicinal product in respect of which no data sheet has been issued prior to the coming into operation of these regulations—

(*a*) the particulars referred to in regulation 2(1)(*b*) of these regulations may specify a date, which shall not be later than 31st January 1976, as the date upon and after which a data sheet will be sent or delivered to any relevant practitioner as referred to in that regulation, and

(*b*) in the event of a date being so specified in accordance with sub-paragraph (*a*) of this paragraph the provisions of regulation 2(4) of these regulations shall not take effect until such date.

Offences

4. 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 2 years or to both.

Barbara Castle,
Secretary of State for Social Services.

28th July 1975.

John Morris,
Secretary of State for Wales.

1st August 1975.

William Ross,
Secretary of State for Scotland.

4th August 1975.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 6th day of August 1975.

(L.S.)

N. Dugdale,
Permanent Secretary.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations provide that particulars relating to medicinal products for human use in certain advertisements issued in professional publications are not to be inconsistent with the relevant data sheet and that such advertisements must contain a notice that a data sheet relating to the product advertised will be sent on request to any doctor or dentist. The regulations also provide that 3 copies of the data sheet must be sent or delivered to the licensing authority not more than 15 months before the issue of any such advertisements. Regulation 3 provides temporary relief from these requirements in certain circumstances and regulation 4 makes it an offence to contravene the regulations and imposes penalties.

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