STATUTORY INSTRUMENTS

1975 No. 298

MEDICINES

The Medicines (Advertising of Medicinal Products) Regulations 1975

Made - - - -	*3rd March* 1975
Laid before Parliament	*11th March* 1975
Coming into Operation	*31st March* 1975

The Secretaries of State respectively concerned with health in England and in Wales, the Secretary of State concerned with health and with agriculture in Scotland, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred by section 95(1)(*a*) 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)** and the Veterinary Products Committee**(d)**, hereby make the following regulations:—

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines (Advertising of Medicinal Products) Regulations 1975 and shall come into operation on 31st March 1975.

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

"the Act" means the Medicines Act 1968;

"medicinal product" includes substances or articles specified in the Medicines (Surgical Materials) Order 1971**(e)**;

"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;

(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 Northern Ireland Departments 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. 1970/1304 (1970 III, p. 4335).
(e) S.I. 1971/1267 (1971 II, p. 3632).

"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.

Advertisements relating to medicinal products for which there is a product licence of right

2.—(1) Subject to the following provisions of these regulations, no advertisement, other than a reference advertisement or trade advertisement, relating to a medicinal product in respect of which there is a product licence being a licence of right, shall be issued by a commercially interested party or by any person at the request or with the consent of a commercially interested party unless one or more of the conditions specified in paragraph (2) of this regulation are satisfied.

(2) The conditions referred to in the preceding paragraph are that—

(i) such product licence is deemed, by virtue of section 47(4) and (5) of the Act, to have incorporated therein the standard provisions contained in paragraphs 9 to 11 of Part I of Schedule 1 to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971**(b)** as amended**(c)** (which paragraphs were added by the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1974**(d)**), or

(ii) such product licence has been varied under section 30 of the Act so as to include provisions identical or equivalent to the standard provisions contained in the said paragraphs 9 to 11, or

(iii) the licensing authority have consented in writing to the issue of the advertisement in question or, in the case of a particular advertisement, the licensing authority have been notified in writing that it is intended to issue the advertisement and have not, during the period of 42 days from being so notified, signified in writing that, for any of the purposes referred to in section 95(4) of the Act, that particular advertisement ought not to be issued.

(a) 1889 c. 63.
(b) S.I. 1971/972 (1971 II, p. 2809).
(c) S.I. 1972/1226 (1972 II, p. 3708).
(d) S.I. 1974/1523 (1974 III, p. 5811).

(3) Where such product licence relates to a medicinal product in respect of which an exemption from the restrictions imposed by section 7 of the Act would have applied by virtue of Article 2(1) of the Medicines (Exemption from Licences) (Foods and Cosmetics) Order 1971**(a)** as amended**(b)** were it not for the provisions of Article 2(3) of that order, the condition contained in paragraph (2)(ii) of this regulation shall be deemed to be satisfied—

(i) in the case of an advertisement relating to such medicinal product directed to the public, if such product licence has been varied so as to include a provision identical or equivalent to the standard provision contained in the said paragraph 10, or

(ii) in the case of an advertisement relating to such medicinal product directed to practitioners, if such product licence has been varied so as to include a provision identical or equivalent to the standard provision contained in the said paragraph 10 and provisions equivalent to the standard provisions contained in the said paragraphs 9 and 11 but limited so as to apply only to advertisements directed to practitioners.

Temporary provisions

3. The prohibition imposed by regulation 2(1) of these regulations shall not apply during a period of 3 months from the date of coming into operation of these regulations in the case of the issue of an advertisement relating to a medicinal product in respect of which an application has been made to the licensing authority for the variation of the relevant product licence so as to include the appropriate provisions referred to in regulation 2(2)(ii), 2(3)(i) or 2(3)(ii) of these regulations.

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.

17th February 1975.

John Morris,
Secretary of State for Wales.

20th February 1975.

William Ross,
Secretary of State for Scotland.

24th February 1975.

(a) S.I. 1971/1410 (1971 II, p. 3945). **(b)** S.I. 1973/2079 (1973 III, p. 7182).

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 27th February 1975.

(L.S.) *Frederick Peart*,
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 3rd day of March 1975.

(L.S.) *Norman Dugdale*,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 3rd day of March 1975.

(L.S.) *J. A. Young*,
Permanent Secretary.

EXPLANATORY NOTE

(*This Note is not part of the Regulations.*)

These Regulations apply only in relation to medicinal products in respect of which there is a product licence of right. The regulations provide that the issue of advertisements relating to such medicinal products is prohibited unless the relevant product licence includes certain provisions relating to advertisements or the licensing authority have given their consent or they have not specified, within a limited time, that a particular advertisement should not be issued. Regulation 3 makes temporary provisions permitting the issue of advertisements for a limited period where an application to vary the product licence has been made and regulation 4 provides that it shall be an offence to contravene the regulations and imposes penalties.

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