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STATUTORY INSTRUMENTS

1974 No. 1523

MEDICINES

The Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1974

Made - - - -	*9th September 1974*
Laid before Parliament	*18th September 1974*
Coming into Operation	*1st November 1974*

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 47(1) of the Medicines Act 1968 and now vested in them (**1**) 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, hereby make the following regulations:—

Citation, interpretation and commencement

1. These regulations, which may be cited as the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1974, shall be read as one with the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**2**) as amended(**3**) (hereinafter referred to as "the principal regulations") and shall come into operation on 1st November 1974.

Amendment of Regulation 2(1) of the principal regulations

2. Regulation 2(1) of the principal regulations (definitions) shall be amended by adding immediately after the definition of "the Act" the following definition:-

""advertisement" has the meaning assigned to it by section 92 of the Act;".

(**1**) 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 1, 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).

(**2**) (1971 II, p. 2809).

(**3**) S.I. 1972/1226 (1972 II, p. 3708).

Amendment of Part I of Schedule 1 to the principal regulations

3. In Part I of Schedule 1 to the principal regulations (standard provisions for product licences including product licences of right) immediately after paragraph 8 there shall be added the following paragraphs:—

"**9.**—(1) Subject to sub-paragraphs (2) and (3) below, the licence holder shall not issue, cause another person to issue or consent to the issue of advertisements relating to medicinal products to which the licence relates containing particulars as to the uses, nature or effects of such products or warnings concerning those products unless the terms of the advertisements in so far as they relate to such particulars or warnings correspond to, or differ to an extent that is not material from,—

(a) the terms of the provisions of the licence relating to such particulars or warnings, or

(b) where the provisions of the licence do not relate to such particulars or warnings, the terms stated in the application on which the licence was granted relating to such particulars or warnings, or the terms stated in a notice in writing given by the licence holder relating to such particulars or warnings and sent or delivered to the licensing authority not less than 42 days (or such shorter period as the authority may allow) before the first issue of the advertisements.

(2) The licence holder shall be required to comply with the provisions in sub-paragraph (1) above when (and only when) he has been so notified in writing by the licensing authority in respect of advertisements of any particular kind specified in such notification.

(3) Notwithstanding the provisions of sub-paragraph (1) above, where the terms of advertisements relating to such particulars or warnings as aforesaid have been stated in an application or notice in circumstances to which sub-paragraph (1)(b) above applies and the licence holder has been informed in writing by the licensing authority, not later than either the date on which the licence was granted or 21 days after the receipt of the notice under sub-paragraph (1)(b) above (whichever is the later), that, for any of the purposes referred to in section 95(4) of the Act, such terms ought not to be included in advertisements or ought only to be so included in a modified form, the licence holder shall not issue, cause another person to issue or consent to the issue of any advertisement of a kind specified in the notification under sub-paragraph (2) above containing such terms or, as the case may be, such terms other than in a modified form, unless the consent of the licensing authority has been given in writing.

10. The licence holder shall, whenever so required by the licensing authority, furnish particulars of any advertisement it is proposed to issue in respect of any medicinal product to which the licence relates, such particulars to include the contents and form of the proposed advertisements, the means, medium or media by which it is to be issued and the time and manner of such issue.

11. The licence holder shall, as soon as is reasonably possible, comply or take all steps that are in the circumstances necessary to ensure compliance with any direction in writing given by the licensing authority that, for any of the purposes referred to in section 95(4) of the Act,—

(a) advertisements of any particular kind specified in such direction relating to medicinal products to which the licence relates, ought not to be issued or, if such advertisements have already been issued, ought not to be issued again, or ought not to be issued or issued again except in circumstances specified in such direction, or

(b) the terms or form of such advertisements or the manner in which such advertisements are, or are to be, issued ought to be modified in a manner specified in such direction, or

(c) precautions as to the use, or warnings as to the effect, of such products ought to be included in such advertisements.".

Barbara Castle
2nd September 1974 — Secretary of State for Social Services

William Ross
6th September 1974 — Secretary of State for Scotland

John Morris
3rd September 1974 — Secretary of State for Wales

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 5th September 1974.

L.S.

Frederick Peart
Minister of Agriculture, Fisheries and Food

Norman Dugdale
Permanent Secretary
Department of Health and Social Services for Northern Ireland
9th September 1974

J. A. Young
Permanent Secretary
9th September 1974 — Department of Agriculture for Northern Ireland

EXPLANATORY NOTE

These Regulations amend the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971, by adding to the standard provisions which may be incorporated in product licences further standard provisions regarding the contents, terms, form, issue and manner of issue of advertisements relating to medicinal products.