STATUTORY INSTRUMENTS

1977 No. 1039

MEDICINES

The Medicines (Standard Provisions for Licences and Certificates) Amendment (No. 2) Regulations 1977

Made - - - -	*16th June 1977*
Laid before Parliament	*23rd June 1977*
Coming into Operation	*14th July 1977*

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.—(1) These regulations may be cited as the Medicines (Standard Provisions for Licences and Certificates) Amendment (No. 2) Regulations 1977 and shall come into operation on 14th July 1977.

(2) These regulations 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").

Amendment of Part I of Schedule 1 to the principal regulations

2. After paragraph 11 of Part I of Schedule 1 to the principal regulations (standard provisions for product licences including product licences of right) there shall be inserted the following paragraphs—

(**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 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 section 1(3) of and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

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

(**3**) The relevant amending instrument is S.I. 1974/1523 (1974 III, p. 5811).

"**12.**—(1) Where the licence relates to a medicinal product which has been or is to be imported—

(a) where the licensing authority have required the production of an undertaking given by or on behalf of the manufacturer of the medicinal product in accordance with section 19(3)(a) of the Act the licence holder shall ensure that the medicinal product is not sold or supplied unless the medicinal product has been manufactured or assembled in the premises in respect of which the undertaking has been given;

(b) the licence holder shall ensure that the medicinal product is not sold or supplied unless the medicinal product has been manufactured or assembled in such premises and in such circumstances as to comply with the relevant conditions specified in the Schedule to the Medicines (Manufacturer's Undertakings for Imported Products) Regulations 1977(**4**) but so that for the purpose of this sub-paragraph references to those regulations shall not be construed as a reference to those regulations as amended by any regulations subsequent to the grant of the licence.

In this paragraph, "relevant conditions" means the conditions so specified except, where an undertaking under section 19(3)(b) has been given, any of such conditions that are not included in such an undertaking, or where such an undertaking has not been given, any of such conditions as the licensing authority may exclude at the time of the grant or renewal of the licence or may subsequently exclude in connection with an application by the licence holder under section 47(6) of the Act that the standard provisions should be incorporated in the licence subject to exceptions or modifications.

(2) The licence holder shall inform the licensing authority of any information supplied to him pursuant to paragraphs 6 and 8 of the Schedule to the Medicines (Manufacturer's Undertakings for Imported Products) Regulations 1977.

13. Where the licence is a licence of right which has been renewed by the licensing authority and at any time after the licence has been renewed regulations are made which amend the principal regulations by inserting additional standard provisions in this Part of this Schedule the licence holder shall, before the end of the period of three months from the date upon which such regulations come into operation, apply to vary the provisions of the licence to incorporate provisions having the like effect as the provisions so inserted in this Part of this Schedule.".

David Ennals
30th May 1977 — Secretary of State for Social Services

John Morris
2nd June 1977 — Secretary of State for Wales

Bruce Millan
14th June 1977 — Secretary of State for Scotland

(**4**) S.I.1977/1038(1977 II, p. 2950).

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 10th June 1977.

L.S.

John Silkin
Minister of Agriculture, Fisheries and Food

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 15th day of June 1977.

L.S.

N. Dugdale
Permanent Secretary

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 16th day of June 1977.

L.S.

J. A. Young
Permanent Secretary

EXPLANATORY NOTE

These Regulations further amend the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 and add to Schedule 1 of the principal regulations further standard provisions which may be incorporated in product licences. Paragraph 12 of Schedule 1 relates to imported medicinal products and paragraph 13 relates to product licences of right which have been renewed.