STATUTORY INSTRUMENTS

1993 No. 2539

MEDICINES

The Medicines (Standard Provisions for Licences and Certificates) Amendment (No. 2) Regulations 1993

Made - - - -	*21st October 1993*
Laid before Parliament	*28th October 1993*
Coming into force - -	*29th November 1993*

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Wales and 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 upon them by sections 47(1) and 129(5) of the Medicines Act 1968(**1**) or, as the case may be, those conferred by the said provisions and now vested in them(**2**) 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 these Regulations(**3**), hereby make the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Medicines (Standard Provisions for Licences and Certificates) Amendment (No. 2) Regulations 1993, and shall come into force on29th November 1993.

Amendment of Schedule 1 to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971

2.—(1) Part I of Schedule 1 to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**4**) (standard provisions for product licences including product licences of right) shall be amended in accordance with the following paragraphs of this regulation.

(**1**) 1968 c. 67. The expression "the Ministers", used in section 47(1), is defined in section 1(1) of that Act as amended by S.I. 1969/388, Schedule 1.

(**2**) 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); in the case of the Secretary of State concerned with agriculture in Wales by virtue of article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272); 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) ofSchedule 1 to, the Northern Ireland Act 1974 (c. 28).

(**3**) *(See* section 129(6) of the Medicines Act 1968.

(**4**) S.I. 1971/972; relevant amending instruments are S.I. 1974/1523, 1977/1039 and 1983/1730.

(2) After paragraph 1 there shall be inserted the following paragraphs—

"(1A) Where the licence relates to a medicinal product for human use, the licence holder shall not recommend the use of the medicinal product to which the licence relates for any indication other than the indications specified in the licence.

(1B) Where the licence relates to a medicinal product for human use, the licence holder may sell or supply the medicinal product to which the licence relates only in the same strength and pharmaceutical form, and to the same specification in terms of active constituents and of the finished product, as specified in the licence.

(1C) Where the licence relates to a medicinal product for human use, the licence holder may sell or supply the medicinal product to which the licence relates only where that product has been manufactured by the manufacturers specified, at the sites of manufacture specified, and by the method specified, in the licence.".

(3) At the beginning of paragraphs 2(1) and (2) and 3, there shall be inserted the words "Where the licence relates to a medicinal product which is not for human use,".

(4) After paragraph 14 there shall be inserted the following paragraphs—

"(15) Where the licence relates to a medicinal product for human use, the holder of that licence shall, in relation to that medicinal product, in order that the licensing authority may monitor the continuing assessment of the benefits and risks of that product—

(a) provide the licensing authority forthwith with any new information not in his original application, and

(b) inform the licensing authority forthwith of any change to the information contained in any documents, samples and other material submitted with his application for grant of the licence.

(16) In relation to a medicinal product for human use which the licensing authority have specified, on granting the licence, to be one to which Part 4G of the Annex to Council Directive 75/318/EEC(**5**) as amended applies, and for which the licensing authority have accordingly identified a programme of studies for, and have specified a period for, the purposes of this provision,—

(a) the licence holder shall, within that period, carry out and complete that programme and provide the licensing authority with details of the results of that programme, and

(b) any leaflet, data sheet or other medical information relating to that product shall draw the attention of persons qualified to prescribe or supply that product to the fact that the particulars available concerning the product are as yet inadequate in certain specified respects.".

Signed by authority of the Secretary of State for Health

Tom Sackville
Parliamentary Under Secretary of State
Department of Health

15th October 1993

(**5**) OJ No. L147, 9.6.1975, p.1. The Directive has been amended by Council Directive 89/341/EEC (OJ No. L142, 25.5.1989, p.11), and the annex to the Directive has been substituted by Commission Directive 91/507/EEC(OJ No. L270, 26.9.1991, p.32).

John Redwood
19th October 1993 Secretary of State for Wales

Fraser of Carmyllie
15th October 1993 Minister of State, Scottish Office

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 18th October 1993.

Gillian Shephard
Minister of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 21st October 1993.

F A Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 18th October 1993.

W J Hodges
Permanent Secretary

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 ("the principal Regulations") by imposing additional requirements to be incorporated into standard provisions for product licences relating to medicinal products.

Regulation 2(2) inserts paragraphs 1A, 1B and 1C into Part I of Schedule 1 to the principal Regulations (standard provisions for product licences including product licences of right). These provide that a medicinal product for human use shall only be recommended for use for specified indications, that it shall be in the same pharmaceutical strength and form and of the same specification specified in the licence and that it shall be manufactured by the manufacturers and at the sites and by the methods specified in the licence.

Regulation 2(3) amends paragraphs 2 and 3 of Part I of Schedule 1 to the principal Regulations so that those paragraphs apply only to medicinal products which are not for human use. In relation to medicinal products for human use, the similar provisions of new paragraph 15 apply (inserted by regulation 2(4)). This paragraph implements part of the third indent in the Introduction to the Annex to Council Directive 75/318/EEC (OJNo. L147, 9.6.1975, p.1) ("the Directive"), as substituted by Commission Directive 91/507/EEC (OJ No. L270, 26.9.1991, p.32), requiring the licence holder to provide the licensing authority with details of any changes to the information in the documentation accompanying his application for the grant of a licence, together with any new information.

Regulation 2(4) also inserts paragraph 16 into Part I of Schedule 1 to the principal Regulations, to implement paragraphs (a) and (c) of Part 4G of the new Annex to the Directive. This paragraph imposes special requirements for medicinal products for human use in respect of which comprehensive information could not have been provided on the application for the grant of the licence because, for example, the indications for the product are encountered so rarely that comprehensive information cannot be obtained.

The Medicines (Applications for Grant of Product Licences–Products for Human Use) Regulations 1993 (S.I.1993/2538) also implement requirements of the new Annex to the Directive as well as those of other Directives.