STATUTORY INSTRUMENTS

1992 No. 3272

MEDICINES

The Medicines (Standard Provisions for Licences and Certificates) Amendment (No. 2) Regulations 1992

Made - - - -	*22nd December 1992*
Laid before Parliament	*23rd December 1992*
Coming into force - -	*1st January 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 section 47(1) 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, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Standard Provisions for Licences and Certificates) Amendment (No. 2) Regulations 1992, and shall come into force on 1st January 1993.

(2) In these Regulations, "the Principal Regulations" means the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**4**).

(**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) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

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

(**4**) S.I. 1971/972; the relevant amending instruments are S.I. 1972/1226, 1974/1523, 1977/675, 1977/1039, 1977/1053, 1983/1730 and 1992/2846.

Amendment of Schedule 5 to the Principal Regulations

2.—(1) Schedule 5 to the Principal Regulations (standard provisions for product licences including product licences of right relating to certain medicinal products) shall be amended in accordance with the following provisions of this regulation.

(2) There shall be inserted at the beginning of paragraph 3 of Part I the words "Subject to paragraph 3A of this Part of this Schedule,".

(3) After paragraph 3 of Part I there shall be inserted the following paragraph—

"**3A.** Paragraph 3 of this Part of this Schedule shall not apply in respect of a batch of—

(a) blood products,

(b) live vaccines,

(c) immunological medicinal products used in the primary immunization of infants or of other groups at risk,

(d) immunological medicinal products used in public health immunization programmes, or

(e) new immunological medicinal products or immunological medicinal products manufactured using new or altered kinds of technology or new for a particular manufacturer, during a transitional period normally specified in the marketing authorisation, which has been previously examined by the competent authority of a member State other than the United Kingdom and declared to be in accordance with the specifications in a marketing authorisation

which complies with Council Directive 65/65/EEC as amended(**5**).".

(4) In paragraph 4 of Part I for the words "the preceding paragraph" there shall be substituted the words "paragraph 3 of this Part of this Schedule".

Virginia Bottomley
18th December 1992 — Secretary of State for Health

David Hunt
21st December 1992 — Secretary of State for Wales

Fraser of Carmyllie
21st December 1992 — Minister of State, Scottish Office

(**5**) OJ No. L22, 9.2.1965, p.369, as amended by Directives 75/318/EEC (OJ No. L147, 9.6.1975, p.1), 75/319/EEC (OJ No. L147, 9.6.1975, p.13), 83/570/EEC (OJ No. L332, 28.11.1983, p.1), 87/21/EEC (OJ No. L15, 17.1.1987, p.36), 89/341/EEC (OJ No. L142, 25.5.1989, p.11), 89/342/EEC (OJ No. L142, 25.5.1989, p.14), 89/343/EEC (OJ No. L142, 25.5.1989, p.16), and 89/381/EEC (OJ No. L181, 28.6.1989, p.44).

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 22nd December 1992.

L.S.

John Selwyn Gummer
Minister of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 18th December 1992.

L.S.

F. A. Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 18th December 1992.

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"). They implement part of paragraph 3 of Article 4 of each of Council Directives 89/342/EEC relating to immunological products (OJ No.L142, 25.5.1989, p.14) and 89/381/EEC relating to medicinal products derived from human blood or human plasma (OJ No.L181, 28.6.1989, p.44). The remaining parts of Article 4 of each of the above Directives have been implemented by regulations 3 and 4 of the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1992 (S.I.1992 No.2846) ("the Standard Provisions Amendment Regulations"). Article 1 of each of the above Directives has been implemented by regulations 2 and 3 of the Medicines Act 1968 (Amendment) Regulations 1992 (S.I.1992 No.604), regulations 2(a) and (b) of the Medicines (Applications for Grant and Renewal of Licences) (Miscellaneous Amendments) Regulations 1992 (S.I. 1992 No.755) (the "Applications Amendment Regulations"), and regulations 2(2) and (3) of the Standard Provisions Amendment Regulations.Article 2 of each of the above Directives, and Article 3 of Directive 89/342/EEC, have been implemented by regulations 3 and 4 of the Applications Amendment Regulations.

These Regulations provide that the requirement in the Principal Regulations to submit samples of certain medicinal products to the licensing authority (Schedule 5, Part I, paragraphs 3 to 5 of the Principal Regulations) shall not apply in respect of blood products and certain immunological medicinal products for human use where such samples have previously been examined by the competent authority of another member State and declared to be in accordance with the specifications in a marketing authorisation which complies with EC directives concerning the approximation of provisions relating to medicinal products.