STATUTORY INSTRUMENTS

2004 No. 1678

MEDICINES

The Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 2004

Made - - - -	*30 June 2004*
Laid before Parliament	*7 July 2004*
Coming into force - -	*30 July 2004*

The Secretary of State, the Department of Health, Social Services and Public Safety, and the Department of Agriculture and Rural Development, acting jointly, in exercise of the 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, pursuant to section 129(6) of that Act, 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 Regulations 2004 and shall come into force on 30th July 2004.

(2) In these Regulations—

"the principal Regulations" means the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**3**).

(**1**) 1968 c. 67; the expression "the Ministers", which is relevant to the powers being exercised in the making of these Regulations, is defined in section 1(1) of that Act as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388, by article 5 of, and paragraph 1(1) of the Schedule to, S.I. 1999/3142, and by article 5(1) of, and paragraph 15 of Schedule 1 to, S.I 2002/794.

(**2**) In the case of the Secretary of State, by virtue of articles 2(1) and 5 of, and paragraph 1(1) of the Schedule to, S.I. 1999/3142, and articles 3(1)(c) and (7) of, and paragraph 15 to Schedule 1 to S.I.2002/794; and in the case of the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development, by virtue of the powers vested in the Ministers in charge of those Departments by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c. 47), which may now be exercised by the Departments by virtue of section 1(8) of, and paragraph 4(1)(b) of the Schedule to, the Northern Ireland Act 2000 (c. 1); the Departments were renamed by virtue of article 3(4) and (6) of S.I. 1999/283 (N.I.1).

(**3**) S.I. 1971/972.

Amendment of regulation 2(1) of the principal Regulations

2. In paragraph (1) of regulation 2 of the principal Regulations (interpretation) for the definition of "good manufacturing practice" substitute the following—

> ""good manufacturing practice" means the part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use, the principles and guidelines of which are specified in Commission Directive 2003/94/EC(**4**).".

Signed by authority of the Secretary of State for Health

Warner
Parliamentary Under Secretary of State,
Department of Health
29th June 2004

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety

D. C. Gowdy
Permanent Secretary,
Department of Health, Social Services and Public Safety
30th June 2004

Pat Toal
Permanent Secretary,
Department of Agriculture and Rural Development
30th June 2004

(**4**) OJ No. L 262, 14.10.2003, p.22.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 ("the principal Regulations") which specify the standard provisions of licences issued under the Medicines Act 1968. In particular, Schedule 2 to the principal Regulations specifies the standard provisions of licences granted to manufacturers of medicinal products, including the requirement in Article 46 of Directive 2001/83/EC(**5**), relating to medicinal products for human use, to comply with "good manufacturing practice". These Regulations substitute a new definition of "good manufacturing practice" and so implement Commission Directive 2003/94/EC, in so far as that Directive relates to the manufacture of medicinal products for human use, other than "investigational medicinal products" (products used in clinical trial).

A full regulatory impact assessment has not been produced for this instrument as it has no impact on the costs of business. A Transposition Note in relation to the implementation of Commission Directive 2003/94/EC has been placed in the libraries of both Houses of Parliament.

(**5**) OJ No. L 311, 28.11.2001, p.67.