STATUTORY INSTRUMENTS

2004 No. 3224

MEDICINES

The Medicines (Marketing Authorisations and Miscellaneous Amendments) Regulations 2004

Made - - - -	*7th December 2004*
Laid before Parliament	*10th December 2004*
Coming into force - -	*1st January 2005*

The Secretary of State, being a Minister designated(**a**) for the purposes of section 2(2) of the European Communities Act 1972(**b**) in relation to medicinal products, in exercise of the powers conferred by the said section 2(2), hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Medicines (Marketing Authorisations and Miscellaneous Amendments) Regulations 2004 and shall come into force on 1st January 2005.

Amendment of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994

2.—(1) The Marketing Authorisations for Veterinary Medicinal Products Regulations 1994(**c**) are amended as follows.

(2) In regulation 1 (title, commencement and interpretation), for paragraph 4, substitute the following paragraph—

"(4) For the purposes of these Regulations—

(a) "the Committee for Medicinal Products for Veterinary Use" has the same meaning as in Title IV of Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ("Regulation (EC) No. 726/2004");

(b) obligations imposed on applicants under regulation 4(4)(a) and (8), on the Ministers under regulations 5(a) and 11, and on the holders of marketing authorisations under regulation 6(1)(a), shall be construed in accordance with sub-paragraph (c) of this paragraph;

(c) references to "the Agency" in Articles 12, 13, 74, 75 and 91 of Directive 2001/82/EC shall be taken to refer to the European Medicines Agency established by Article 55 of Regulation (EC) No. 726/2004; and

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(**a**) S.I. 1972/1811.
(**b**) 1972 c.68.
(**c**) S.I. 1994/3142; relevant amending instruments are S.I. 1998/1048 and 2002/269

(d) unless the context otherwise requires, any other expressions used have the meanings they bear in Directive 2001/82/EC(**a**).**”**.

(3) In regulation 6 (duties on persons responsible for placing products on the market), in paragraph (2), in sub-paragraph (c), after “Medicines Commission” insert “established under section 2 of the Medicines Act 1968, the Committee for Medicinal Products for Veterinary Use”.

Amendment of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994

3.—(1) The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**b**) (“the 1994 Regulations”) are amended as follows.

(2) In regulation 1 (citation, commencement and interpretation)—

(a) in paragraph (2)—

(i) in the definition of “the 2001 Directive”, after “as amended” insert “by Commission Directive 2003/63/EC(**c**) and Article 1(21), (44), (45) and (54) of Directive 2004/27/EC”,

(ii) after the definition of the “the 2001 Directive” insert the following definition—

““Directive 2004/27/EC” means Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use(**d**);**”**,

(iii) for the definition of “the EMEA” substitute—

““the EMEA” means the European Medicines Agency established by Regulation (EC) No. 726/2004;**”**,

(iv) after the definition of “parallel import licence”, insert the following definition—

““Regulation (EC) No. 726/2004” means Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency(**e**);**”**, and

(v) in the definition of “the relevant Community provisions”—

(aa) omit “and” in both places that word appears, and

(bb) after the entry for “Regulation (EC) No. 1085/2003” insert the following entry—

“and

Title IV of Regulation (EC) No. 726/2004;**”**; and

(b) after paragraph (5), insert the following paragraph—

“(5A) For the purposes of these Regulations—

(a) references to “the Agency” in the 2001 Directive and in Titles I and II of Regulation (EEC) No. 2309/93(**f**) shall be taken to refer to the European Medicines Agency established by Article 55 of Regulation (EC) No. 726/2004; and

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(**a**) OJ No. L311, 28.11.2001, p.1.
(**b**) S.I. 1994/3144; relevant amending instruments are S.I. 2001/795, 2002/236 and 2003/2321.
(**c**) OJ No. L159, 27.6.2003, p.46.
(**d**) OJ No. L136, 30.4.2004, p.34.
(**e**) OJ No. L136, 30.4.2004, p.1.
(**f**) OJ No. L214, 24.08.93, p.1.

(b) references to "the Committee" in the 2001 Directive and in Title II of Regulation (EEC) No. 2309/93 shall be taken to refer to the Committee for Medicinal Products for Human Use specified in Article 56(1)(a) of Regulation (EC) No. 726/2004.".

(3) In Schedule 2 (procedural provisions relating to the grant, renewal, variation, revocation and suspension of United Kingdom marketing authorization), in paragraph 3, for "the Committee for Proprietary Medicinal Products" substitute "the Committee for Medicinal Products for Human Use".

(4) In Schedule 3 (offences, penalties etc.)—

(a) in paragraph (6), after sub-paragraph (c), insert the following sub-paragraph—

"(cc) provide information to the licensing authority as required by the third or fourth paragraphs of Article 23 of the 2001 Directive; or",

(b) after paragraph (6) insert the following paragraph—

"**6A.** Any holder of a United Kingdom marketing authorization who fails to forward to the licensing authority any data requested by the authority pursuant to the final paragraph of Article 23 of the 2001 Directive—

(a) where the licensing authority have served a written notice on the holder under regulation 7(5) in relation to the request, within the time specified in that notice; or

(b) where there is no such notice, promptly,

shall be guilty of an offence.".

(5) In Schedule 6 (transitional provisions), after paragraph 4, insert the following paragraph—

"**4A.** Until 1st July 2008, these Regulations shall apply, in so far as they relate to the package leaflets of medicinal products in respect of which—

(a) a marketing authorization is in force on 1st January 2005,

(b) a United Kingdom marketing authorization is granted, or an application for the grant of such an authorization is made, in the period from 1st January 2005 to 30th June 2005, or

(c) a Community marketing authorization is granted in the period from 1st January 2005 to 29th October 2005,

as if the 2001 Directive had not been amended by Article 1(44) and (45) of Directive 2004/27/EC.".

Amendment of the Terrorism Act 2000

4. In section 63C of the Terrorism Act 2000(**a**) (terrorist attacks abroad on UK nationals, residents and diplomatic staff etc: jurisdiction), in subsection (3), in paragraph (c), for "the European Agency for the Evaluation of Medicinal Products" substitute "the European Medicines Agency".

Amendment of the Health Service Medicines (Control of Prices of Branded Medicines) Regulations 2000

5. In the Health Service Medicines (Control of Prices of Branded Medicines) Regulations 2000(**b**), in regulation 2 (interpretation), in paragraph (1), in paragraph (b) of the definition of "marketing authorisation", for "by the European Agency for the Evaluation of Medicinal Products" substitute "by the European Commission".

(**a**) 2000 c.11; section 63C was inserted by section 52 of the Crime (International Co-operation) Act 2003.
(**b**) S.I 2000/123; as amended by S.I. 2002/236.

Amendment of the Health Service Medicines (Control of Prices of Specified Generic Medicines) Regulations 2000

6. In the Health Service Medicines (Control of Prices of Specified Generic Medicines) Regulations 2000(**a**), in regulation 2 (interpretation), in paragraph (1), in paragraph (b) of the definition of "marketing authorisation", for "by the European Agency for the Evaluation of Medicinal Products" substitute "by the European Commission".

Amendment of the Health Service Medicines (Information on the Prices of Specified Generic Medicines) Regulations 2001

7. In the Health Service Medicines (Information on the Prices of Specified Generic Medicines) Regulations 2001(**b**), in regulation 2 (interpretation), in paragraph (1), in paragraph (b) of the definition of "marketing authorisation", for "by the European Agency for the Evaluation of Medicinal Products" substitute "by the European Commission".

Amendment of the Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003

8. In the Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003(**c**), in regulation 1 (citation, commencement and interpretation), in paragraph (2), in paragraph (a)(ii) of the definition of "unlicensed product", for "the European Agency for the Evaluation of Medicinal Products under" substitute "the European Commission under".

Amendment of the Medicines for Human Use (Clinical Trials) Regulations 2004

9. In the Medicines for Human Use (Clinical Trials) Regulations 2004(**d**), in regulation 2 (interpretation), in paragraph (1), for the definition of "the European Medicines Agency" substitute the following definition—

> **"**"the European Medicines Agency" means the European Medicines Agency established by Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;**"**.

Signed by authority of the Secretary of State for Health

Warner
Parliamentary Under Secretary of State,
Department of Health

7th December 2004

(**a**) S.I 2000/1763; as amended by S.I. 2002/236.
(**b**) S.I 2001/3798; as amended by S.I. 2002/236.
(**c**) S.I. 2003/1680.
(**d**) S.I. 2004/1031.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement certain provisions of Directive 2004/27/EC of the European Parliament and of the Council ("the 2004 Directive") amending Directive 2001/83/EC on the Community code for medicinal products for human use ("the 2001 Directive"), and make consequential amendments to various enactments following the adoption of Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

The 2001 Directive is implemented in part by the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 ("the 1994 Regulations"). Regulation 3(2)(a)(i) and (ii) of these Regulations amends the 1994 Regulations so as to implement Article 1(21), (44), (45) and (54) of the 2004 Directive. These provisions amend the 2001 Directive so as to provide, in relation to medicinal products for human use, that–

(a) marketing authorization holders have additional obligations to provide information and data to the competent authority (Article 1(21) of the 2004 Directive),

(b) package leaflets accompanying such products must be drawn up in accordance with new requirements, in particular that the leaflet must reflect the results of consultations with target patient groups (Article 1(44) and (45)), and

(c) where a change of classification of such a product has been authorised on the basis of significant pre-clinical tests or clinical trials, the competent authority may not refer to the results of those tests or trials, when examining a change of classification for the same substance within one year of the initial change (Article 1(54)).

Regulation 3(4) creates new criminal offences for failures by marketing authorization holders to provide information in accordance with the requirements of the new paragraphs inserted by Article 1(21) of the 2004 Directive. Regulation 3(5) amends the 1994 Regulations so as to make transitional provision for the application of the amendments relating to package leaflets made by Article 1(44) and (45) of the 2004 Directive.

These Regulations, except regulation 3(2)(a)(i) and (ii), (4) and (5), make amendments to the Terrorism Act 2000 and to various statutory instruments consequential on the coming into force of Title IV of Regulation (EC) No. 726/2004. This Regulation revokes and replaces Council Regulation (EEC) No. 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products. Most of Regulation (EC) No. 726/2004 does not apply until 20th November 2005, but Title IV came into force on 20th May 2004. Title IV provides for the establishment and constitution of the European Medicines Agency (which replaces the European Agency for the Evaluation of Medicinal Products), and the constitution of the Committee for Medicinal Products for Human Use and the Committee for Medicinal Products for Veterinary Use (which replace the Committee for Proprietary Medicinal Products and the Committee for Veterinary Medicinal Products, respectively).

A Regulatory Impact Assessment in relation to these Regulations, and a Transposition Note in relation to the implementation of the 2004 Directive, have been placed in the libraries of both Houses of Parliament and copies may be obtained from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

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