STATUTORY INSTRUMENTS

2005 No. 2759

The Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005

Citation and commencement

1. These Regulations may be cited as the Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 and shall come into force—

(a) except for the purposes of the provisions specified in paragraph (b), on 30th October; and

(b) for the purposes of paragraphs (2)(a)(ii) and (vi) and (c), (9)(a), (11)(a) and (14)(e), (f)(i), (iii) to (v) of regulation 2, and paragraphs 3 to 5, 6(b)(iii), 7 to 9, 11, 12 and 17(b) of the Schedule, on 20th November 2005.

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

2.—(1) The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**1**) are amended as follows.

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

(a) in paragraph (2)—

(i) after the definition of "the Act" insert the following definition—

""certificate of registration" means a certificate of registration granted by the licensing authority under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**2**);",

(ii) in the definition of "Community marketing authorization", after "2309/93" insert "or Regulation (EC) No. 726/2004(**3**)",

(iii) in the definition of "the 2001 Directive"—

(aa) after "as amended by Commission Directive 2003/63/EC" insert ", Directive 2004/24/EC"(**4**), and

(bb) omit "Article 1(21), (44), (45) and (54) of ",

(iv) after the definition of "the 2001 Directive" insert the following definition—

""Directive 2004/24/EC" means Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use(**5**);",

(v) for the definition of "EEA State" substitute the following definition—

(**1**) S.I. 1994/3144; relevant amending instruments are S.I 2001/795, 2002/236, 2003/2321, 2004/3224, 2005/50 and 2005/1710.
(**2**) S.I. 1994/105; as amended by S.I. 1994/899, 1995/541, 1996/482, 1998/574, 1999/566, 2001/795, 2002/236 and 542, 2003/625 and 2321, 2004/666 and 2005/2753
(**3**) OJ No. L136, 30.4.2004, p.1.
(**4**) OJ No. L159, 27.6.2003, p.46.
(**5**) OJ No. L136, 30.4.2004, p.85.

""EEA State" means a Member State, Norway, Iceland or Liechtenstein;"

(vi) in the definition of "the relevant Community provisions"—

(aa) omit "Regulation (EEC) No. 2309/93;", and

(bb) omit "Title IV of",

(vii) for the definition of "relevant medicinal product" substitute the following definition—

""relevant medicinal product" means, except in regulation 3A and paragraph 1A of Schedule 3, a medicinal product for human use to which the provisions of the 2001 Directive apply other than—

(a) a traditional herbal medicinal product, or

(b) a homoeopathic medicinal product that fulfils the conditions laid down in Article 14(1) of the 2001 Directive;", and

(viii) after the definition of "supplementary prescriber" insert the following definition—

""traditional herbal registration" means a traditional herbal registration granted by the licensing authority under the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005(**6**);";

(b) omit paragraph (3); and

(c) omit paragraph (5A).

(3) In regulation 3 (marketing authorizations for relevant medicinal products) in paragraph (1) for "paragraphs 1 and 3" substitute "paragraphs 1 and 3 to 5A".

(4) In regulation 3A (borderline products)(**7**)—

(a) in paragraph (1), after "marketing authorization" insert ", traditional herbal registration or certificate of registration";

(b) in paragraph (6), after "marketing authorization" insert ", traditional herbal registration or certificate of registration"; and

(c) after paragraph (7) insert the following paragraph—

"(8) In this regulation, "relevant medicinal product" means a medicinal product for human use to which the provisions of the 2001 Directive apply.".

(5) After regulation 3A (borderline products) insert the following regulation—

"**Immunity from liability for consequences arising from the use in certain cases of an unauthorised medicinal product or the use of a medicinal product for an unauthorised indication**

3B.—(1) This regulation applies where, in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation which may cause harm to humans, the licensing authority recommend or require the use of—

(a) a medicinal product which is not the subject of a Community marketing authorization or a United Kingdom marketing authorization; or

(b) a medicinal product which is the subject of such an authorization, for a therapeutic indication which is not included in the summary of product characteristics under that authorization.

(2) Subject to paragraph (3)—

(**6**) S.I. 2005/2750

(**7**) Regulation 3A was inserted by regulation 3 of S.I. 2000/292.

(a) the holder of a marketing authorization for the product the use of which is recommended or required by the licensing authority;

(b) a manufacturer of that product;

(c) an officer, servant, employee or agent of a person referred to in sub-paragraph (a) or (b); and

(d) a health professional,

shall not be subject to any civil liability for any loss or damage resulting from the use of the product in accordance with the recommendation or requirement.

(3) Paragraph (2) shall not apply in relation to liability under section 2 of the Consumer Protection Act 1987(**8**).

(4) In this regulation, "health professional" means—

(a) a doctor,

(b) a dentist,

(c) a registered nurse (**9**),

(d) a pharmacist,

(e) a person registered in a register of optometrists maintained under section 7 of the Opticians Act 1989(**10**),

(f) a person registered in a register established and maintained under article 5 of the Health Professions Order 2001(**11**),

(g) a registered osteopath as defined by section 41 of the Osteopaths Act 1993(**12**), or

(e) a registered chiropractor as defined by section 43 of the Chiropractors Act 1994(**13**).".

(6) In regulation 4 (applications for the grant, renewal or variation of a United Kingdom marketing authorization)—

(a) for paragraphs (3) and (4), substitute the following paragraph—

"(3) One copy of the application and of any accompanying material shall be supplied to the licensing authority in the English language and where the application or any accompanying material has been translated from another language, one copy of the application or the accompanying material, as the case may be, shall also be supplied in the original language.";

(b) for paragraph (6), substitute the following paragraph—

"(6) For the purposes of Article 10(1) of the 2001 Directive, the period of 8 years (period during which reference medicinal products must have been authorized) there mentioned shall not apply if the application for the authorization of the reference medicinal product was submitted before 30th October 2005.";

(c) after paragraph (6), insert the following paragraphs—

"(6A) Where, by reason of paragraph (6) the period of 8 years does not apply, the applicant shall not be required to provide the results of pre-clinical tests and of clinical

(**8**) 1987 c. 43.
(**9**) S*ee* the definition of "registered", in relation to nurses and midwives, in Schedule 1 to the Interpretation Act 1978, as substituted by S.I. 2002/53 and amended by S.I. 2004/1771.
(**10**) 1989 c. 44.
(**11**) S.I. 2002/254.
(**12**) 1993 c. 21.
(**13**) 1994 c. 17.

trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which has been authorized in an EEA State for not less than 10 years.

(6B) The fourth sub-paragraph of Article 10(1) of the 2001 Directive shall not apply if the application for the initial authorization of the reference medicinal product was submitted before 30th October 2005."; and

(d) in paragraph (9), for "3" substitute "6".

(7) In regulation 5 (consideration, and grant or refusal, of an application for, or renewal or variation of, a United Kingdom marketing authorization)—

(a) for paragraph (4) substitute the following—

"(4) A parallel import licence shall, unless previously renewed or revoked, be valid for the period specified in it, but where an application to renew it is made in accordance with regulation 4(9) it shall remain in force pending the decision of the licensing authority on that application."; and

(b) after paragraph (4), insert the following paragraphs—

"(5) An authorization granted by the licensing authority in accordance with Article 126a of the 2001 Directive shall, unless previously revoked, be valid for the period specified in it.

(6) Subject to paragraph (8), a United Kingdom marketing authorization, other than a parallel import licence shall, unless previously revoked, be valid for an unlimited period unless—

(a) it has not been renewed on the basis of a re-evaluation by the licensing authority of the risk-benefit balance in accordance with, and on the basis of the data set out in, Article 24(2) of the 2001 Directive; or

(b) it has been so renewed, but the licensing authority considers on justified grounds relating to pharmacovigilance that it should be subject to one additional renewal five years after the date of the first renewal, and it has not yet been subject to that additional renewal.

(7) Subject to paragraph (8), where, by reason of paragraph (6), a United Kingdom marketing authorization is not valid for an unlimited period, it shall, unless previously revoked, be valid for a period of five years beginning with the date on which it is granted or was renewed, whichever is the later, but where an application for its renewal is made in accordance with Article 24 of the 2001 Directive the marketing authorization shall remain in force pending the decision of the licensing authority on that application.

(8) Subject to paragraph (9), a United Kingdom marketing authorization (other than a parallel import licence) shall cease to be valid if at any time after it is granted the medicinal product to which it relates is not placed on the market in the United Kingdom for a period of three consecutive years, unless an exemption is granted in accordance with Article 24(6) of the 2001 Directive.

(9) For the purposes of calculating the period of three consecutive years referred to in paragraph (8), no account shall be taken of any period before 30th October 2005.".

(8) In regulation 5A (classification of medicinal products), after paragraph (1) insert the following paragraph—

"(1A) For the purposes of paragraph (1), "marketing authorization" includes an authorization granted by the licensing authority in accordance with Article 126a of the 2001 Directive.".

(9) In regulation 6 (revocation, suspension or variation of a United Kingdom marketing authorization or the suspension of the use or marketing of medicinal products)—

(a) in paragraph (5), for "Council Regulation (EEC) No. 2309/93" substitute "Regulation (EC) No. 726/2004"; and

(b) after paragraph (7), insert the following paragraph—

"(7A) For the purposes of this regulation, "marketing authorization" includes an authorization granted by the licensing authority in accordance with Article 126a of the 2001 Directive.".

(10) In regulation 6A (urgent safety restrictions)—

(a) in paragraph (1), after "marketing authorization" insert "or an authorization granted by the licensing authority in accordance with Article 126a of the 2001 Directive"; and

(b) in paragraph (2), omit "marketing".

(11) In regulation 7 (obligations of holders of marketing authorizations, and offences by holders of marketing authorizations and other persons)—

(a) in paragraph (1), for "Regulation (EEC) No. 2309/93" substitute "Regulation (EC) No. 726/2004";

(b) after paragraph (3), insert the following paragraph—

"(3A) Where a person is authorised by the licensing authority to place a product on the market in accordance with Article 126a of the 2001 Directive, he shall comply with all obligations under Titles V, VI, VIII, IX and XI of that Directive which would apply to him by virtue of those provisions and these Regulations if he were the holder of a United Kingdom marketing authorization for that product."; and

(c) after paragraph (6), insert the following paragraph—

"(7) For the purposes of paragraphs (2), (3), (4) and (6), "marketing authorization" includes an authorization granted by the licensing authority in accordance with Article 126a of the 2001 Directive.".

(12) In regulation 9 (consequential and other amendments of the Act and the Medicines Act 1971), after paragraph (14), insert the following paragraphs—

"(15) Subject to paragraph (16), for the purposes of this regulation, "marketing authorization" includes an authorization granted by the licensing authority in accordance with Article 126a of the 2001 Directive.

(16) Paragraph (15) shall not apply in relation to paragraph (10).".

(13) In Schedule 1 (exemptions and exceptions from the provisions of regulation 3)—

(a) in paragraph 1, after "responsibility" insert ", in order to fulfil the special needs of those patients";

(b) in paragraph 2, for sub-paragraph (e) substitute the following sub-paragraph—

"(e) if the relevant medicinal product is manufactured or assembled in the United Kingdom, or imported into the United Kingdom from a third country, the product—

(i) is manufactured, assembled or imported by the holder of a manufacturer's licence which relates specifically to the manufacture, assembly or import of relevant medicinal products to which paragraph 1 applies; or

(ii) has been manufactured, assembled or imported as an investigational medicinal product by the holder of a manufacturing authorization granted by the licensing authority for the purposes of regulation 36 of the Medicines for Human Use (Clinical Trials) Regulations 2004(**14**); and"; and

(**14**) S.I. 2004/1031.

(c) after paragraph 5 insert the following paragraph—

"**5A.** Regulation 3(1) shall not apply to a medicinal product for which there is in force an authorization to place the product on the market granted by the licensing authority in accordance with Article 126a of the 2001 Directive.".

(14) In Schedule 3 (offences, penalties etc)—

(a) paragraph 1A(**15**) is amended as follows—

(i) paragraph 1A shall be renumbered as sub-paragraph (1) of that paragraph,

(ii) in paragraph (a) of sub-paragraph (1), after "marketing authorization", in both places those words appear, insert ", traditional herbal registration or certificate of registration",

(iii) in paragraph (b) of sub-paragraph (1), after "marketing authorization", in both places those words appear, insert ", traditional herbal registration or certificate of registration", and

(iv) after sub-paragraph (1), insert the following sub-paragraph—

"(2) In this paragraph, "relevant medicinal product" means a medicinal product for human use to which the provisions of the 2001 Directive apply.".

(b) after paragraph 1A insert the following paragraph—

"**1AA.** Any person who places a generic medicinal product on the market before the period of —

(a) in a case where during the first eight years after the grant of the initial marketing authorization of the reference medicinal product the holder of that authorization is granted an authorization for a new therapeutic indication of significant clinical benefit as set out in the fourth sub-paragraph 4 of Article 10(1) of the 2001 Directive, eleven years; and

(b) in any other case, ten years

has elapsed from the date of that initial authorization, shall be guilty of an offence.";

(c) in paragraph 2, after "paragraph 1" insert "or paragraph 1AA";

(d) after paragraph 2, insert the following paragraph—

"**2A.** Any person who distributes a relevant medicinal product by way of wholesale dealing contrary to regulation 3(1)(b) shall be guilty of an offence.";

(e) in paragraphs 4, 7, 8, 9 and 10 for "Council Regulation (EEC) No. 2309/93" substitute "Regulation (EC) No. 726/2004";

(f) in paragraph 6—

(i) in sub-paragraph (b), for "Article 15.1 of Council Regulation (EEC) No 2309/93" substitute "Article 16.1 of Regulation (EC) No. 726/2004",

(ii) in sub-paragraph (cc), after "Article 23" insert "or the first paragraph of Article 23a",

(iii) in sub-paragraph (d), for "Article 15.2 of Council Regulation (EEC) No 2309/93" substitute "Article 16.2 of Regulation (EC) No. 726/2004" and, after the semi-colon, omit "or",

(iv) after sub-paragraph (d), insert the following sub-paragraph—

"(dd) provide information to the EMEA as required by the first or second paragraphs of Article 13(4) of Regulation No. 726/2004; or", and

(**15**) Paragraph 1A was inserted by regulation 4(1) of S.I. 2000/292.

(v) in sub-paragraph (e), for "Article 15.3 of Council Regulation (EEC) No 2309/93" substitute "Article 16.3 of Regulation (EC) No. 726/2004";

(g) in paragraph 6A, after "Article 23", insert "or of Article 23a";

(h) after paragraph 6A, insert the following paragraphs—

"**6B.** Subject to paragraph 17, any person who is the holder of a United Kingdom marketing authorization who fails, not less than two months before an interruption in the placing on the market of the product to which the authorization relates, to notify the licensing authority that the product is to cease to be placed on the market, shall be guilty of an offence.

6C. Subject to paragraph 17, any person who is the holder of a Community or United Kingdom marketing authorization who fails to ensure appropriate and continued supplies pursuant to the second paragraph of Article 81 of the 2001 Directive shall be guilty of an offence.

6D. Any person who is the holder of a Community marketing authorization who fails to provide the EMEA with any data requested pursuant to the final paragraph of Article 13(4) or the final paragraph of Article 26 of Regulation (EC) No. 726/2004—

(a) within the time specified in the request, if a time within which to provide the data to the EMEA is so specified; or

(b) promptly, if no such time is specified,

shall be guilty of an offence.

6E. Any person who is the holder of a Community or United Kingdom marketing authorization who communicates to the general public information—

(a) relating to pharmacovigilance concerns about the product to which the authorization relates;

(b) without having previously communicated, or without simultaneously communicating, such information to the EMEA, in the case of a product for which there is a Community marketing authorization, or otherwise the licensing authority,

shall be guilty of an offence.

6F. Any person—

(a) who is the holder of a Community or United Kingdom marketing authorization; and

(b) who fails to ensure that the information which he communicates to the general public, the licensing authority or the EMEA relating to pharmacovigilance concerns about the product to which his authorization relates is presented objectively and is not misleading,

shall be guilty of an offence.";

(i) in paragraph 17, after "paragraph" insert "6B, 6C,"; and

(j) after paragraph 17, insert the following paragraphs—

"**Definitions**

18. For the purposes of paragraphs 1, 3, 3A, 4, 5, 6E, 6F, 11, 12 and 16, "marketing authorization" includes an authorization granted by the licensing authority in accordance with Article 126a of the 2001 Directive.

19. For the purposes of paragraphs 7, 8 , 9 and 10 the Directive requirements referred to in those paragraphs are deemed to apply in relation to the holder of an authorization granted by the licensing authority in accordance with Article 126a of the 2001 Directive as they apply to the holder of a marketing authorization.".

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

"**4B.** Until 30th October 2010, these Regulations shall apply, in so far as they relate to the labelling of medicinal products in respect of which a marketing authorization was granted before 30th October 2005, as if the 2001 Directive had not been amended by Article 1(40), (41) and (42) of Directive 2004/27/EC.".

Amendments of the Patents Act 1977

3. In section 60 of the Patents Act 1977(**16**) (meaning of infringement)—

(a) in subsection (5), after paragraph (h), insert the following—

"(i) it consists of—

(i) an act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of paragraphs 1 to 5 of article 13 of Directive 2001/82/EC or paragraphs 1 to 4 of article 10 of Directive 2001/83/EC, or

(ii) any other act which is required for the purpose of the application of those paragraphs.", and

(b) in subsection (7), at the end insert the following—

""Directive 2001/82/EC" means Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products(**17**) as amended by Directive 2004/28 of the European Parliament and of the Council(**18**);

"Directive 2001/83/EC" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, as amended by Directive 2002/98/EC of the European Parliament and of the Council, by Commission Directive 2003/63/EC and by Directives 2004/24/EC and 2004/27/EC of the European Parliament and of the Council".

Consequential amendments to enactments

4. The provisions of the enactments specified in the Schedule shall be amended as there specified.

Signed by authority of the Secretary of State for Health

Warner
Minister of State
Department

6th October 2005

(**16**) 1977 c. 37.
(**17**) OJ No. L311, 28.11.2001, p.1.
(**18**) OJ No. L136, 30.4.2004, p.58.