

2009 No. 2820

MEDICINES

**The Medicines for Human Use (Marketing Authorisations Etc.)
Amendment Regulations 2009**

<i>Made</i> - - - -	<i>19th October 2009</i>
<i>Laid before Parliament</i>	<i>26th October 2009</i>
<i>Coming into force</i> - -	<i>1st January 2010</i>

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(a). He has been designated for the purposes of that section in relation to medicinal products(b).

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 2009 and shall come into force on 1st January 2010.

(2) In these Regulations, the “1994 Regulations” means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(c).

Amendment of paragraph 7 of Schedule 2 to the 1994 Regulations

2. For paragraph 7 of Schedule 2 to the 1994 Regulations (requirement to consult the appropriate committee) substitute the following paragraph—

“7.—(1) The licensing authority shall not, at any time while this Schedule applies—

- (a) unless the circumstances described in sub-paragraph (2) apply, refuse to grant or renew the authorization applied for; or
- (b) revoke, vary or (subject to paragraph 12 of this Schedule) suspend an authorization,

on grounds relating to safety, quality or efficacy, except after consultation with the appropriate committee.

(2) The circumstances for the purposes of sub-paragraph (1)(a) are—

- (a) the licensing authority has requested the applicant to supply information which the licensing authority regards as relevant to enable the application to be determined; and
- (b) the information has not been supplied to the licensing authority within the relevant period.

(3) In sub-paragraph (2) the “relevant period” is—

(a) 1972 c.68; section 2(2) was amended by the Legislative and Regulatory Reform Act 2006 (c.51), section 27(1)(a).
(b) S.I. 1972/1811.
(c) S.I. 1994/3144; the relevant amending instrument is S.I. 2005/1094.

- (a) where the licensing authority has completed its initial full assessment of the application, the period of six months beginning with the date on which the licensing authority requested the applicant to supply the information referred to in sub-paragraph (2)(a); or
 - (b) where the licensing authority has completed its assessment of any supplemental information, the period of three months beginning with the date on which the licensing authority requested the applicant to supply the information referred to in sub-paragraph (2)(a).
- (4) The applicant may at any time before the relevant period has expired submit a request to the licensing authority for the period to be extended.
- (5) An applicant requesting an extension of the relevant period must provide grounds on which the request is made.
- (6) Where an applicant has submitted a request in accordance with sub-paragraphs (4) and (5), the licensing authority may extend the relevant period in accordance with the request provided it considers that the grounds on which it is made are exceptional.”.

Signed by authority of the Secretary of State for Health

19th October 2009

Mike O'Brien
Minister of State
Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (“the 1994 Regulations”) by removing the obligation on the licensing authority to consult the appropriate committee (as defined in regulation 1(2) of the 1994 Regulations) before refusing to grant or renew a marketing authorization on grounds relating to safety, quality or efficacy in any case where the licensing authority has requested the applicant to supply information which it regards as relevant to enable the application to be determined and the relevant period has expired without that information having been supplied. The Regulations make provision as to determination of the relevant period and the possibility of its extension at the request of the applicant.

An impact assessment of the effect that this instrument will have on the costs of business is available from the MHRA at Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

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£4.00