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STATUTORY INSTRUMENTS

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**2008 No. 3097**

**MEDICINES**

**The Medicines for Human Use (Marketing  
Authorisations Etc.) Amendment Regulations 2008**

*Made* - - - - *3rd December 2008*  
*Laid before Parliament* *8th December 2008*  
*Coming into force* - - *29th December 2008*

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(1). He has been designated for the purposes of that section in relation to medicinal products(2).

**Citation, commencement and interpretation**

1.—(1) These Regulations may be cited as the Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 2008 and shall come into force on 29th December 2008.

(2) In these Regulations, the “1994 Regulations” means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(3).

**Amendment of regulation 1 of the 1994 Regulations**

2. In regulation 1 of the 1994 Regulations (citation, commencement and interpretation), in paragraph (2)—

- (a) in the definition of “the Clinical Trials Directive”, after “human use” insert “as amended by the Paediatric Regulation”;
- (b) in the definition of “the 2001 Directive”, for “and Directive 2004/27/EC” substitute “, Directive 2004/27/EC and the Paediatric Regulation”;
- (c) after the definition of “national homoeopathic product”, insert the following definition—  
““the Paediatric Regulation” means Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use

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(1) 1972 c.68; section 2(2) was amended by the Legislative and Regulatory Reform Act 2006 (c.51), section 27(1)(a).  
(2) S.I. 1972/1811.  
(3) S.I. 1994/3144; relevant amending instruments are S.I. 2001/795, 2002/236, 2003/2321, 2004/3224, 2005/50, 2005/1710 and 2005/2759.

- and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004(4), as amended by Regulation (EC) No 1902/2006 of the European Parliament and of the Council amending Regulation 1901/2006 on medicinal products for paediatric use(5);”;
- (d) in the definition of “Regulation (EC) No 726/2004”, after “European Medicines Agency” insert “, as amended by the Paediatric Regulation”; and
- (e) in the definition of “the relevant Community provisions”—
- (i) omit “and”, and
  - (ii) after “Regulation (EC) No 726/2004;” insert—  
“and  
the Paediatric Regulation;”.

### **Amendment of Schedule 3 to the 1994 Regulations**

- 3.—**(1) Schedule 3 to the 1994 Regulations (offences, penalties etc) shall be amended as follows.
- (2) In paragraph 6—
- (a) in sub-paragraph (cc), in paragraph (i) and (ii), after “Directive” (in each place that it occurs) insert “as read in accordance with paragraph 6AA”;
  - (b) at the end of sub-paragraph (e), insert “or”; and
  - (c) after sub-paragraph (e), insert the following sub-paragraph—  
“(f) submit an annual report to the EMEA as required by Article 34(4) of the Paediatric Regulation.”.
- (3) After paragraph 6, insert the following paragraph—  
“**6AA.** The information that must be provided as specified in paragraph 6(cc)(i) and (ii) includes information arising from use of the product —
- (a) in a country which is not an EEA State;
  - (b) outside the terms of the marketing authorization,
- including use in clinical trials as defined in Article 2(a) of the Clinical Trials Directive.”.
- (4) After paragraph 6B, insert the following paragraphs—  
“**6BA.** Where the holder of a United Kingdom marketing authorization (“H”) has benefited from rewards or incentives under Article 36, 37 or 38 of the Paediatric Regulation in relation to the product to which the authorization relates and the periods of protection provided pursuant to those Articles have expired in relation to H, H shall be guilty of an offence if H discontinues the placing of that product on the market without previously, in compliance with Article 35 of the Paediatric Regulation—
- (a) transferring the marketing authorization of that product to another person who has declared his intention to continue to place that product on the market, or
  - (b) allowing use by such a person of the pharmaceutical, pre-clinical and clinical documentation contained in the file on that product on the basis of Article 10c of the 2001 Directive.
- 6BB.** Where the holder of a United Kingdom marketing authorization (“H”) has benefited from rewards or incentives under Articles 36, 37 or 38 of the Paediatric Regulation in relation to the product to which the authorization relates, and the periods of protection

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(4) OJNo. L378, 27.12.06, p.1.

(5) OJ No. L378, 27.12.06, p. 20.

provided pursuant to those Articles have expired in relation to H, H shall be guilty of an offence if H discontinues the placing of that product on the market without informing the EMEA in compliance with Article 35 of the Paediatric Regulation, at least 6 months before the discontinuation, of H's intention to discontinue the placing of the product on the market.”.

(5) After paragraph 6F, insert the following paragraph—

“**6G.** Any person who—

- (a) is the holder of a United Kingdom marketing authorization;
- (b) obtains a paediatric indication in respect of the product to which the marketing authorization relates following completion of an agreed paediatric investigation plan;
- (c) has marketed that product for other indications prior to obtaining that paediatric indication; and
- (d) fails to place the product on the market taking account of the paediatric indication within two years of the date on which the paediatric indication is authorised as required by Article 33 of the Paediatric Regulation,

shall be guilty of an offence.”.

(6) For sub-paragraph (d) of paragraph 10 substitute —

“(d) provide as soon as is reasonably practicable to the licensing authority any other information relevant to the evaluation of the benefits and risks afforded by a medicinal product, including appropriate information arising from use of the product—

- (i) in post authorization safety studies;
- (ii) in a country which is not an EEA State;
- (iii) outside the terms of the marketing authorization, including use in clinical trials as defined in Article 2(a) of the Clinical Trials Directive.”.

(7) In paragraph 11, for “or of Schedule 5 or 5A to these Regulations,” substitute “, Schedule 5 or 5A to these Regulations or Article 28 or 32 of the Paediatric Regulation,”.

(8) In paragraph 12, for “or Schedule 5 or 5A to these Regulations,” substitute “, Schedule 5 or 5A to these Regulations or Article 28 or 32 of the Paediatric Regulation,”.

(9) After paragraph 13A, insert the following paragraph—

“**13B.**—(1) Any person established in the United Kingdom to whom a decision by the EMEA in respect of a paediatric investigation plan is addressed shall be guilty of an offence if the plan relates to a product which does not have a Community marketing authorization and the person fails to—

- (a) enter into the database referred to in Article 11 of the Clinical Trials Directive within a period of six months beginning with the date that the decision was received, the details set out in that Article in relation to clinical trials referred to in the paediatric investigation plan and carried out in third countries as required by Article 41(1) of the Paediatric Regulation; or
- (b) submit the results of those clinical trials to the EMEA within a period of six months beginning with the date that the trial ended as required by Article 41(2) of the Paediatric Regulation.

(2) Where the holder of a United Kingdom marketing authorization (“H”) instigates or conducts a paediatric clinical trial in the United Kingdom in respect of the product to which the authorization relates and the trial is not included in a paediatric investigation plan, H

shall be guilty of an offence if H fails to submit the results of that trial to the EMEA within a period of six months beginning with the date that the trial ended, as required by Article 41(2) of the Paediatric Regulation.

(3) Where the holder of a United Kingdom marketing authorization (“H”) has instigated or conducted a paediatric clinical trial in the United Kingdom which ended on or after 26th January 2007 but before 29th December 2008 in respect of the product to which the authorization relates and the trial is not included in a paediatric investigation plan, H shall be guilty of an offence if H fails to submit the results of that trial to the EMEA on or before 29th June 2009, as required by Article 41(2) of the Paediatric Regulation.

(4) Any person who—

- (a) is the sponsor of a paediatric clinical trial in the United Kingdom in respect of a medicinal product—
  - (i) with a United Kingdom marketing authorization, but where the trial is not instigated by the marketing authorization holder; or
  - (ii) without a United Kingdom or Community marketing authorization, where the trial is not included in a paediatric investigation plan; and
- (b) fails to submit the results of that trial to the EMEA within the period of six months beginning on the date that the trial ended as required by Article 41(2) of the Paediatric Regulation,

shall be guilty of an offence.

(5) Any person who—

- (a) has sponsored a paediatric clinical trial in the United Kingdom in respect of a medicinal product—
  - (i) with a United Kingdom marketing authorization, but who is not the marketing authorization holder; or
  - (ii) without a United Kingdom or Community marketing authorization, where the trial is not included in a paediatric investigation plan and ended on or after 26th January 2007 but before 29th December 2008; and
- (b) fails to submit the results of that trial to the EMEA on or before 29th June 2009 as required by Article 41(2) of the Paediatric Regulation,

shall be guilty of an offence.

(6) Any holder of a United Kingdom marketing authorization who—

- (a) has knowledge of a paediatric study in respect of the product to which the authorization relates that ended on or before 25th January 2007; and
- (b) fails to submit that paediatric study to the licensing authority on or before 29th June 2009 as required by Article 45(1) of the Paediatric Regulation,

shall be guilty of an offence.

(7) Any holder of a United Kingdom marketing authorization who—

- (a) sponsors a paediatric study in respect of the product to which the authorization relates; and
- (b) fails to submit the results to the licensing authority within a period of six months beginning with the date that the trial ended as required by Article 46(1) of the Paediatric Regulation,

shall be guilty of an offence.

(8) Any holder of a United Kingdom marketing authorization who—

- (a) has sponsored a paediatric study in respect of the product to which the authorization relates which ended on or after 26th January 2007 but before 29th December 2008; and
  - (b) fails to submit the results to the licensing authority on or before 29th June 2009 as required by Article 46(1) of the Paediatric Regulation,
- shall be guilty of an offence.
- (9) For the purposes of this paragraph—
- (a) a “clinical trial” has the meaning given by regulation 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004<sup>(6)</sup>; and
  - (b) a “paediatric clinical trial” means a clinical trial conducted in whole or in part on persons under the age of 18 years.”.
- (10) In paragraph 17, for “6B, 6C, 10A or 13A” substitute “6B, 6BA, 6BB, 6C, 6G, 10A, 13A or 13B”.

#### **Amendment of the Medicines Act 1968**

##### **4. In the Medicines Act 1968<sup>(7)</sup>—**

- (a) in section 8 (provisions as to manufacture and wholesale dealing), in subsection (2B), in the definition of “marketing authorization”—
  - (i) in paragraph (a), for “Directive [2001/83/EC](#)” substitute “the 2001 Directive”, and
  - (ii) in paragraph (b), after “Council Regulation ([EEC](#)) [2309/93](#)” insert “or under 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<sup>(8)</sup>”; and
- (b) in section 132 (general interpretation provisions), in subsection (1), in the definition of “the 2001 Directive”—
  - (i) in paragraph (c), omit the final “and”, and
  - (ii) after paragraph (d), insert—

“and

    - (e) Regulation ([EC](#)) No [1901/2006](#) of the European Parliament and of the Council on medicinal products for paediatric use and amending Regulation ([EEC](#)) No [1768/92](#), Directive [2001/20/EC](#), Directive [2001/83/EC](#) and Regulation ([EC](#)) No [726/2004](#)<sup>(9)</sup>”.

#### **Amendment of the Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008**

- 5. In regulation 1(2) of the Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008<sup>(10)</sup>, in the definition of “repeatable prescription” omit “with”.**

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<sup>(6)</sup> [S.I. 2004/1031](#), to which there are amendments not relevant to these Regulations.

<sup>(7)</sup> [1968 c.67](#).

<sup>(8)</sup> OJ No. L136, 30.4.2004, p.1; Regulation ([EC](#)) No [726/2004](#) has been amended by Regulation ([EC](#)) No [1901/2006](#) (OJ No. L378, 27.12.06, p.1).

<sup>(9)</sup> OJ No. L378, 27.12.06, p.1; Regulation ([EC](#)) No [1901/2006](#) has been amended by Regulation ([EC](#)) No [1902/2006](#) of the European Parliament and of the Council amending Regulation 1901/2006 on medicinal products for paediatric use (OJ No. L378, 27.12.06, p.20).

<sup>(10)</sup> [S.I. 2008/1692](#).

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**Status:** *This is the original version (as it was originally made). UK  
Statutory Instruments are not carried in their revised form on this site.*

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Signed by authority of the Secretary of State for Health.

3rd December 2008

*Dawn Primarolo*  
Minister of State,  
Department of Health

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations provide for the enforcement in the United Kingdom of Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004, as amended by Regulation (EC) No 1902/2006 of the European Parliament and of the Council amending Regulation 1901/2006 on medicinal products for paediatric use (the Paediatric Regulation). The Paediatric Regulation establishes a scheme of obligations and incentives to encourage the development of, and improve access to, medicines for children.

The Paediatric Regulation is enforced through amendments to the Medicines for Human Use (Marketing Authorisation Etc.) Regulations (“the 1994 Regulations”). The 1994 Regulations are the primary piece of legislation through which Community obligations in relation to medicines are implemented.

These Regulations also further amend the 1994 Regulations in connection with transposition of Directive 2001/83 of the European Parliament and Council on the Community Code relating to medicinal products for human use.

Regulation 2 amends regulation 1 of the 1994 Regulations to update references to Community legislation amended by the Paediatric Regulation; and to identify the Paediatric Regulation as a “relevant Community Provision” for the purpose of the 1994 Regulations.

Regulation 3 amends Schedule 3 to the 1994 Regulations by inserting various additional criminal offences through which provisions of the Paediatric Regulation can be enforced and by clarifying certain aspects of the information-reporting obligations in that Schedule.

Regulation 4 updates references to Community legislation in the Medicines Act 1968 to include the Paediatric Regulation.

Regulation 5 corrects a typographical error in the Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008.

A full impact assessment has not been produced for this instrument as no impact on the private and voluntary sectors is foreseen.