

Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 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 (Text with EEA relevance)

TITLE I

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- Article 1 This Regulation lays down rules concerning the development of medicinal...
- Article 2 In addition to the definitions laid down in Article 1 of...

CHAPTER 2

Paediatric committee

- Article 3 (1) By 26 July 2007, a Paediatric Committee shall be...
- Article 4 (1) The Paediatric Committee shall be composed of the following...
- Article 5 (1) When preparing its opinions, the Paediatric Committee shall use...
- Article 6 (1) The tasks of the Paediatric Committee shall include the...

TITLE II

MARKETING AUTHORISATION REQUIREMENTS

CHAPTER 1

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- Article 7 (1) An application for marketing authorisation under Article 6 of Directive...
- Article 8 In the case of authorised medicinal products which are protected...
- Article 9 Articles 7 and 8 shall not apply to products authorised...
- Article 10 In consultation with the Member States, the Agency and other...

CHAPTER 2

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- Article 11 (1) Production of the information referred to in point (a)...

- Article 12 The Paediatric Committee may of its own motion adopt an...
Article 13 (1) The applicant may, on the grounds set out in...
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- Article 15 (1) Where the intention is to apply for a marketing...
Article 16 (1) In the case of the applications for marketing authorisation...
Article 17 (1) Following receipt of a proposed paediatric investigation plan which...
Article 18 As soon as the Paediatric Committee adopts an opinion, whether...
Article 19 If, having considered a paediatric investigation plan, the Paediatric Committee...

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- Article 20 (1) At the same time as the paediatric investigation plan...
Article 21 (1) At the same time as the Paediatric Committee adopts...

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- Article 22 If, following the decision agreeing the paediatric investigation plan, the...

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- Article 23 (1) The competent authority responsible for granting marketing authorisation shall...
Article 24 If, when conducting the scientific assessment of a valid application...

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TITLE III

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CHAPTER 1

Marketing authorisation procedures for applications falling within the scope of Articles 7 and 8

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CHAPTER 2

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Article 31 Without prejudice to Article 3(2) of Regulation (EC) No 726/2004, an application...

CHAPTER 3

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TITLE IV

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- Article 36 (1) Where an application under Article 7 or 8 includes...
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TITLE VI

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- Article 41 (1) The European database created by Article 11 of Directive 2001/20/EC...
Article 42 Member States shall collect available data on all existing uses...
Article 43 (1) On the basis of the information referred to in...
Article 44 (1) The Agency shall, with the scientific support of the...
Article 45 (1) By 26 January 2008, any paediatric studies already completed...
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Fees, community funding, penalties and reports

- Article 47 (1) Where an application for a paediatric use marketing authorisation...
Article 48 The Community contribution provided for in Article 67 of Regulation (EC)...
Article 49 (1) Without prejudice to the Protocol on the Privileges and...
Article 50 (1) On the basis of a report from the Agency,...

Section 2

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- Article 51 (1) The Commission shall be assisted by the Standing Committee...

CHAPTER 2

Amendments

- Article 52 Regulation (EEC) No 1768/92 is hereby amended as follows: in Article 1,...
- Article 53 In Article 11 of Directive 2001/20/EC, the following paragraph shall be...
- Article 54 In Article 6 of Directive 2001/83/EC, the first subparagraph of paragraph...
- Article 55 Regulation (EC) No 726/2004 is hereby amended as follows: Article 56(1) shall...

CHAPTER 3

Final provisions

- Article 56 The requirement laid down in Article 7(1) shall not apply to...
- Article 57 (1) This Regulation shall enter into force on the thirtieth...
Signature

- (1) [OJ C 267, 27.10.2005, p. 1.](#)
- (2) Opinion of the European Parliament of 7 September 2005 ([OJ C 193 E, 17.8.2006, p. 225](#)), Council Common Position of 10 March 2006 ([OJ C 132 E, 7.6.2006, p. 1](#)) and Position of the European Parliament of 1 June 2006 (not yet published in the Official Journal). Council Decision of 23 October 2006.
- (3) [OJ L 121, 1.5.2001, p. 34.](#)
- (4) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ([OJ L 136, 30.4.2004, p. 1](#)).
- (5) [OJ L 311, 28.11.2001, p. 67.](#) Directive as last amended by Directive 2004/27/EC ([OJ L 136, 30.4.2004, p. 34](#)).
- (6) [OJ L 182, 2.7.1992, p. 1.](#) Regulation as last amended by the 2003 Act of Accession.
- (7) [OJ L 18, 22.1.2000, p. 1.](#)
- (8) [OJ L 184, 17.7.1999, p. 23.](#) Decision as amended by Decision 2006/512/EC ([OJ L 200, 22.7.2006, p. 11](#)).