

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

INTRODUCTORY PROVISIONS

CHAPTER 1

Subject matter and definitions

- 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

General authorisation requirements

- 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

Waivers

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

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 1901/2006 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

- Article 12 The Paediatric Committee may of its own motion adopt an...
Article 13 (1) The applicant may, on the grounds set out in...
Article 14 (1) The Agency shall maintain a list of all waivers....

CHAPTER 3

Paediatric investigation plan

Section 1

Requests for agreement

- 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...

Section 2

Deferrals

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

Section 3

Modification of a paediatric investigation plan

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

Section 4

Compliance with the paediatric investigation plan

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

CHAPTER 4

Procedure

- Article 25 (1) Within ten days of its receipt, the Agency shall...

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CHAPTER 5

Miscellaneous provisions

Article 26 Any legal or natural person developing a medicinal product intended...

TITLE III

MARKETING AUTHORISATION PROCEDURES

Article 27 Save where otherwise provided in this Title, marketing authorisation procedures...

CHAPTER 1

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

Article 28 (1) Applications may be submitted in accordance with the procedure...

Article 29 In the case of medicinal products authorised under Directive 2001/83/EC,...

CHAPTER 2

Paediatric use marketing authorisation

Article 30 (1) Submission of an application for a paediatric use marketing...

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

CHAPTER 3

Identification

Article 32 (1) Where a medicinal product is granted a marketing authorisation...

TITLE IV

POST-AUTHORISATION REQUIREMENTS

Article 33 Where medicinal products are authorised for a paediatric indication following...

Article 34 (1) In the following cases, the applicant shall detail the...

Article 35 If a medicinal product is authorised for a paediatric indication...

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TITLE V

REWARDS AND INCENTIVES

- Article 36 (1) Where an application under Article 7 or 8 includes...
Article 37 Where an application for a marketing authorisation is submitted in...
Article 38 (1) Where a paediatric use marketing authorisation is granted in...
Article 39 (1) In addition to the rewards and incentives provided for...
Article 40 (1) Funds for research into medicinal products for the paediatric...

TITLE VI

COMMUNICATION AND COORDINATION

- 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...
Article 46 (1) Any other marketing authorisation holder-sponsored studies which involve the...

TITLE VII

GENERAL AND FINAL PROVISIONS

CHAPTER 1

General provisions

Section 1

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

Standing committee

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

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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

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- (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](#)).

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Changes and effects yet to be applied to :

- [Regulation revoked in part by S.I. 2019/775 Sch. 9 para. 1\(l\)](#)