

Regulation (EC) No 726/2004 of the European Parliament and of the Council
of 31 March 2004 laying down Union procedures for the authorisation
and supervision of medicinal products for human and veterinary use and
establishing a European Medicines Agency (Text with EEA relevance) (revoked)

TITLE I

DEFINITIONS AND SCOPE

- Article 1 The purpose of this Regulation is to lay down Union...
Article 2 The definitions laid down in Article 1 of Directive 2001/83/EC...
Article 3 (1) No medicinal product appearing in the Annex may be...
Article 4 (1) Applications for the marketing authorisations referred to in
Article...

TITLE II

AUTHORISATION AND SUPERVISION OF
MEDICINAL PRODUCTS FOR HUMAN USE

Chapter 1

Submission and examination of applications — Authorisations

- Article 5 (1) A Committee for Medicinal Products for Human Use is...
Article 6 (1) Each application for the authorisation of a medicinal
product...
Article 7 In order to prepare its opinion, the Committee for Medicinal...
Article 8 (1) Upon receipt of a written request from the Committee...
Article 9 (1) The Agency shall forthwith inform the applicant if the...
Article 10 (1) Within 15 days after receipt of the opinion referred...
Article 10a (1) After the granting of a marketing authorisation, the Agency...
Article 10b (1) The Commission is empowered to adopt delegated acts in...
Article 11 If an applicant withdraws an application for a marketing
authorisation...
Article 12 (1) The marketing authorisation shall be refused if, after
verification...
Article 13 (1) Without prejudice to Article 4(4) and (5) of Directive
2001/83/EC, a...
Article 14 (1) Without prejudice to paragraphs 4 and 5 of this...
Article 14-a (1) In duly justified cases, to meet unmet medical needs...
Article 14a The marketing authorisation holder shall incorporate any
conditions referred to...
Article 14b (1) The marketing authorisation holder shall notify the Agency
forthwith...
Article 15 The granting of authorisation shall not affect the civil or...

Chapter 2

Supervision and penalties

- Article 16 (1) After a marketing authorisation has been granted in accordance...
- Article 16a (1) Variations shall be classified in different categories depending on...
- Article 16b A marketing authorisation may be transferred to a new marketing...
- Article 17 The applicant or the holder of a marketing authorisation shall...
- Article 18 (1) In the case of medicinal products manufactured within the...
- Article 19 (1) The supervisory authorities for manufacturing and imports shall be...
- Article 20 (1) Where the supervisory authorities or the competent authorities of...
- Article 20a Where the Agency concludes that a holder of a marketing...

Chapter 3

Pharmacovigilance

- Article 21 (1) The obligations of marketing authorisation holders laid down in...
- Article 22 The obligations of marketing authorisation holders laid down in Article...
- Article 23 (1) The Agency shall, in collaboration with the Member States,...
- Article 24 (1) The Agency shall, in collaboration with the Member States...
- Article 25 The Agency shall, in collaboration with the Member States, develop...
- Article 25a The Agency shall, in collaboration with the national competent authorities...
- Article 26 (1) The Agency shall, in collaboration with the Member States...
- Article 27 (1) The Agency shall monitor selected medical literature for reports...
- Article 28 (1) The obligations of marketing authorisation holders and of Member...
- Article 28a (1) Regarding medicinal products for human use authorised in accordance...
- Article 28b (1) For non-interventional post-authorisation safety studies concerning medicinal products for...
- Article 28c (1) The Agency shall collaborate with the World Health Organisation...
- Article 28d At the request of the Commission, the Agency shall participate...
- Article 28e The Agency and the Member States shall cooperate to continuously...
- Article 28f The Agency shall perform regular independent audits of its pharmacovigilance...
- Article 29 The Commission shall make public a report on the performance...

TITLE III

AUTHORISATION AND SUPERVISION OF VETERINARY MEDICINAL PRODUCTS

Chapter 1

Submission and examination of applications — Authorisations

- Article 30 (1) A Committee for Medicinal Products for Veterinary Use is...
- Article 31 (1) Each application for the authorisation of a medicinal product...
- Article 32 (1) In order to prepare its opinion, the Committee for...
- Article 33 (1) Upon receipt of a written request from the Committee...
- Article 34 (1) The Agency shall forthwith inform the applicant if the...
- Article 35 (1) Within 15 days after receipt of the opinion referred...
- Article 36 If an applicant withdraws an application for a marketing authorisation...
- Article 37 (1) The marketing authorisation shall be refused if, after verification...
- Article 38 (1) Without prejudice to Article 71 of Directive 2001/82/EC, a...
- Article 39 (1) Without prejudice to paragraphs 4 and 5, a marketing...
- Article 40 The granting of authorisation shall not affect the civil or...

Chapter 2

Supervision and sanctions

- Article 41 (1) After an authorisation has been granted in accordance with...
- Article 42 The applicant or the holder of a marketing authorisation shall...
- Article 43 (1) In the case of veterinary medicinal products manufactured within...
- Article 44 (1) The supervisory authorities shall be responsible for verifying on...
- Article 45 (1) Where the supervisory authorities or the competent authorities of...

Chapter 3

Pharmacovigilance

- Article 46 For the purpose of this Chapter, Article 77(2) of Directive...
- Article 47 The Agency, acting in close cooperation with the national pharmacovigilance...
- Article 48 The holder of the marketing authorisation for a veterinary medicinal...
- Article 49 (1) The holder of the marketing authorisation for a veterinary...
- Article 50 Each Member State shall ensure that all suspected serious adverse...
- Article 51 The Commission, in consultation with the Agency, Member States and...
- Article 52 The Agency shall cooperate with international organisations concerned with veterinary...

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 726/2004 of the European Parliament and of the Council. (See end of Document for details)

Article 53 The Agency and the Member States' competent authorities shall cooperate...

Article 54 The Commission may adopt any amendment which may be necessary...

TITLE IV

THE EUROPEAN MEDICINES AGENCY — RESPONSIBILITIES AND ADMINISTRATIVE STRUCTURE

Chapter 1

Tasks of the Agency

Article 55 A European Medicines Agency is hereby established. The Agency shall...

Article 56 (1) The Agency shall comprise: (a) the Committee for Medicinal...

Article 57 (1) The Agency shall provide the Member States and the...

Article 58 (1) The Agency may give a scientific opinion, in the...

Article 59 (1) The Agency shall take care to ensure early identification...

Article 60 At the request of the Commission, the Agency shall, in...

Article 61 (1) Each Member State shall, after consultation of the Management...

Article 61a (1) The Pharmacovigilance Risk Assessment Committee shall be composed of...

Article 62 (1) Where, in accordance with this Regulation, any of the...

Article 63 (1) The membership of the committees referred to in Article...

Article 64 (1) The Executive Director shall be appointed by the Management...

Article 65 (1) The Management Board shall consist of one representative of...

Article 66 The Management Board shall: adopt an opinion on the rules...

Chapter 2

Financial Provisions

Article 67 (1) Estimates of all the revenue and expenditure of the...

Article 68 (1) The Executive Director shall implement the budget of the...

Article 69 (1) In order to combat fraud, corruption and other unlawful...

Article 70 (1) The structure and the level of the fees referred...

Chapter 3

General Provisions governing the Agency

Article 71 The Agency shall have legal personality. In all Member States...

Article 71a The Agency shall have its seat in Amsterdam, the Netherlands.

Article 72 (1) The contractual liability of the Agency shall be governed...

Article 73 Regulation (EC) No 1049/2001 of the European Parliament and of the...

Article 73a Decisions taken by the Agency under Regulation (EC) No 1901/2006...

- Article 74 The Protocol on the Privileges and Immunities of the European...
- Article 75 The staff of the Agency shall be subject to the...
- Article 76 Members of the Management Board, members of the committees referred...
- Article 77 The Commission may, in agreement with the Management Board and...
- Article 78 (1) The Management Board shall, in agreement with the Commission,...
- Article 79 The Management Board shall, in the case of veterinary medicinal...
- Article 80 To ensure an appropriate level of transparency, the Management Board,...

TITLE V

GENERAL AND FINAL PROVISIONS

- Article 81 (1) All decisions to grant, refuse, vary, suspend, withdraw or...
- Article 82 (1) Only one authorisation may be granted to an applicant...
- Article 83 (1) By way of exemption from Article 6 of Directive...
- Article 84 (1) Without prejudice to the Protocol on the Privileges and...
- Article 84a (1) The Commission may impose financial penalties in the form...
- Article 85 This Regulation shall not affect the competences vested in the...
- Article 86 At least every ten years, the Commission shall publish a...
- Article 86a By 2019, the Commission shall review the regulatory framework for...
- Article 87 (1) The Commission shall be assisted by the Standing Committee...
- Article 87a In order to harmonise the performance of the pharmacovigilance activities...
- Article 87b (1) The power to adopt delegated acts is conferred on...
- Article 87c
- Article 87d
- Article 88 Regulation (EEC) No 2309/93/EC is hereby repealed. References to the repealed...
- Article 89 The periods of protection provided for in Articles 14(11) and...
- Article 90 This Regulation shall enter into force on the twentieth day...
Signature

ANNEX I

MEDICINAL PRODUCTS TO BE AUTHORISED BY THE UNION

1. Medicinal products developed by means of one of the following...
 - 1a. Advanced therapy medicinal products as defined in Article 2 of Regulation...
 2. Medicinal products for veterinary use intended primarily for use as...
 3. Medicinal products for human use containing a new active substance...

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC)
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4. Medicinal products that are designated as orphan medicinal products pursuant...

ANNEX II

LIST OF THE OBLIGATIONS REFERRED TO IN ARTICLE 84A

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EC) No 726/2004 of the European Parliament and of the Council.