

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 (Text with EEA relevance)

TITLE IV

**THE EUROPEAN MEDICINES AGENCY —  
RESPONSIBILITIES AND ADMINISTRATIVE STRUCTURE**

Chapter 2

**Financial Provisions**

*Article 67*

1 Estimates of all the revenue and expenditure of the Agency shall be prepared for each financial year, corresponding to the calendar year, and shall be shown in the budget of the Agency.

2 The revenue and expenditure shown in the budget shall be in balance.

3 The Agency's revenue shall consist of a contribution from the Community and fees paid by undertakings for obtaining and maintaining Community marketing authorisations and for other services provided by the Agency.

The European Parliament and the Council (hereinafter referred to as ‘the budgetary authority’) shall re-examine, when necessary, the level of the Community contribution on the basis of an evaluation of needs and taking account of the level of fees.

4 Activities relating to pharmacovigilance, to the operation of communications networks and to market surveillance shall receive adequate public funding commensurate with the tasks conferred.

5 The expenditure of the Agency shall include staff remuneration, administrative and infrastructure costs, and operating expenses as well as expenses resulting from contracts entered into with third parties.

6 Each year the Management Board, on the basis of a draft drawn up by the Executive Director, shall produce an estimate of revenue and expenditure for the Agency for the following financial year. This estimate, which shall include a draft establishment plan, shall be forwarded by the Management Board to the Commission by 31 March at the latest.

7 The estimate shall be forwarded by the Commission to the budgetary authority together with the preliminary draft general budget of the European Union.

8 On the basis of the estimate, the Commission shall enter in the preliminary draft general budget of the European Union the estimates it deems necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Article 272 of the Treaty.

9 The budgetary authority shall authorise the appropriations for the subsidy to the Agency.

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*Status: Point in time view as at 30/12/2008.*

*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, Chapter 2. (See end of Document for details)*

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The budgetary authority shall adopt the establishment plan for the Agency.

10 The budget shall be adopted by the Management Board. It shall become final following final adoption of the general budget of the European Union. Where appropriate, it shall be adjusted accordingly.

11 Any modification of the establishment plan and of the budget shall be the subject of an amending budget, which is forwarded for the purposes of information to the budgetary authority.

12 The Management Board shall, as soon as possible, notify the budgetary authority of its intention to implement any project which may have significant financial implications for the funding of its budget, in particular any projects relating to property such as the rental or purchase of buildings. It shall inform the Commission thereof.

Where a branch of the budgetary authority has notified its intention to deliver an opinion, it shall forward its opinion to the Management Board within a period of six weeks from the date of notification of the project.

#### *Article 68*

1 The Executive Director shall implement the budget of the Agency.

2 By 1 March at the latest following each financial year, the Agency's accounting officer shall communicate the provisional accounts to the Commission's accounting officer together with a report on the budgetary and financial management for that financial year. The Commission's accounting officer shall consolidate the provisional accounts of the institutions and decentralised bodies in accordance with Article 128 of the Financial Regulation applicable to the general budget of the European Communities<sup>(1)</sup> (hereinafter referred to as the 'general Financial Regulation').

3 By 31 March at the latest following each financial year, the Commission's accounting officer shall submit the Agency's provisional accounts to the Court of Auditors, together with a report on the budgetary and financial management for that financial year. The report on the budgetary and financial management for the financial year shall also be forwarded to the European Parliament and the Council.

4 On receipt of the Court of Auditors' observations on the Agency's provisional accounts, pursuant to Article 129 of the general Financial Regulation, the Executive Director shall draw up the Agency's final accounts under his own responsibility and submit them to the Management Board for an opinion.

5 The Management Board of the Agency shall deliver an opinion on the Agency's final accounts.

6 The Executive Director shall, by 1 July at the latest following each financial year, forward the final accounts to the European Parliament, the Council, the Commission and the Court of Auditors, together with the Management Board's opinion.

7 The final accounts shall be published.

8 The Agency's Executive Director shall send the Court of Auditors a reply to its observations by 30 September at the latest. He shall also send this reply to the Management Board.

9 The Executive Director shall submit to the European Parliament, at the latter's request, any information required for the smooth application of the discharge procedure for the financial year in question, as laid down in Article 146(3) of the general Financial Regulation.

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10 The European Parliament, on a recommendation from the Council acting by a qualified majority, shall, before 30 April of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for year N.

11 The financial rules applicable to the Agency shall be adopted by the Management Board after the Commission has been consulted. They may not depart from Commission Regulation (EC, Euratom) No 2343/2002 of 19 November 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities<sup>(2)</sup>, unless specifically required for the Agency's operation and with the Commission's prior consent.

#### *Article 69*

1 In order to combat fraud, corruption and other unlawful activities the provisions of Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF)<sup>(3)</sup> shall apply without restriction.

2 The Agency shall accede to the Interinstitutional Agreement of 25 May 1999 concerning internal investigations by the European Anti-Fraud Office (OLAF) and shall issue, without delay, the appropriate provisions applicable to all the employees of the Agency.

#### *Article 70*

1 The structure and the level of the fees referred to in Article 67(3) shall be established by the Council acting under the conditions provided for by the Treaty on a proposal from the Commission, once the Commission has consulted organisations representing the interests of the pharmaceutical industry at Community level.

2 However, provisions shall be adopted in accordance with the procedure referred to in Article 87(2), establishing the circumstances in which small and medium-sized enterprises may pay reduced fees, defer payment of the fee, or receive administrative assistance.

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- (1) Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities ([OJ L 248, 16.9.2002, p. 1](#)).
- (2) [OJ L 357, 31.12.2002, p. 72](#).
- (3) [OJ L 136, 31.5.1999, p. 1](#).

**Status:**

Point in time view as at 30/12/2008.

**Changes to legislation:**

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