

**COUNCIL REGULATION (EC) No 1647/2003**

**of 18 June 2003**

**amending Regulation (EEC) No 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the evaluation of Medicinal Products**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 308 thereof,

Having regard to the proposal from the Commission <sup>(1)</sup>,

Having regard to the opinion of the European Parliament <sup>(2)</sup>,

Having regard to the opinion of the Court of Auditors <sup>(3)</sup>,

Whereas:

- (1) Certain provisions of Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products <sup>(4)</sup> should be brought into line with Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities <sup>(5)</sup> (hereinafter referred to as 'the general Financial Regulation'), and in particular Article 185 thereof.
- (2) The general principles and limits governing right of access to documents provided for in Article 255 of the Treaty have been laid down by Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents <sup>(6)</sup>.
- (3) When Regulation (EC) No 1049/2001 was adopted, the three institutions agreed in a joint declaration that the agencies and similar bodies should implement rules conforming to those of that Regulation.

(4) Appropriate provisions should therefore be included in Regulation (EEC) No 2309/93 to make Regulation (EC) No 1049/2001 applicable to the European Agency for the Evaluation of Medicinal Products, as should a provision for appeals against a refusal of access to documents.

(5) Regulation (EEC) No 2309/93 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

*Article 1*

Regulation (EEC) No 2309/93 is hereby amended as follows.

1. In Article 55:

(a) the fifth indent of paragraph 2 shall be replaced by the following:

‘— for the preparation of the draft statement of estimates of the Agency's revenue and expenditure, and execution of its budget,’

(b) paragraph 3 shall be replaced by the following:

‘Each year the Executive Director shall submit a draft work programme for the coming year to the Management Board for approval, making a distinction between the Agency's activities concerning medicinal products for human use and those concerning veterinary medicinal products.’

(c) paragraph 4 shall be deleted.

2. Article 56(5) shall be replaced by the following:

‘5. The Management Board shall adopt the annual report on the Agency's activities and forward it by 15 June at the latest to the European Parliament, the Council, the Commission, the European Economic and Social Committee, the Court of Auditors and the Member States.

6. The Agency shall forward annually to the budgetary authority any information relevant to the outcome of the evaluation procedures.’

<sup>(1)</sup> OJ C 331 E, 31.12.2002, p. 61.

<sup>(2)</sup> Opinion delivered on 27.3.2003 (not yet published in the Official Journal).

<sup>(3)</sup> OJ C 285, 21.11.2002, p. 4.

<sup>(4)</sup> OJ L 214, 24.8.1993, p. 1. Regulation as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).

<sup>(5)</sup> OJ L 248, 16.9.2002, p. 1, with Corrigendum in OJ L 25, 30.1.2003, p. 43.

<sup>(6)</sup> OJ L 145, 31.5.2001, p. 43.

3. Article 57 shall be replaced by the following:

*'Article 57*

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.

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

5. 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.

6. The estimate shall be forwarded by the Commission to the European Parliament and the Council (hereinafter referred to as the 'budgetary authority') together with the preliminary draft general budget of the European Union.

7. 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.

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

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

9. The budget of the Agency 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.

10. 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.'

4. The following Article shall be inserted:

*'Article 57a*

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 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 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.

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 (\*) unless specifically required for the Agency's operation and with the Commission's prior consent.

(\*) OJ L 357, 31.12.2002, p. 72, with Corrigendum in OJ L 2, 7.1.2003, p. 39.'

5. The following Article shall be inserted:

*'Article 63a*

1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and

Commission documents (\*) shall apply to documents held by the Agency.

2. The Management Board shall adopt the practical arrangements for implementing Regulation (EC) No 1049/2001 within six months of entry into force of Council Regulation (EC) No 1647/2003 of 18 June 2003 amending Regulation (EEC) No 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (\*\*).

3. Decisions taken by the Agency pursuant to Article 8 of Regulation (EC) No 1049/2001 may form the subject of a complaint to the Ombudsman or of an action before the Court of Justice, under the conditions laid down in Articles 195 and 230 of the Treaty respectively.

(\*) OJ L 145, 31.5.2001, p. 43.

(\*\*) OJ L 245, 29.9.2003, p. 19.'

*Article 2*

This Regulation shall enter into force on the first day of the month following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Luxembourg, 18 June 2003.

*For the Council*

*The President*

G. DRYS