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 ([1]),

Having regard to the opinion of the European Parliament ([2]),

Having regard to the opinion of the Court of Auditors ([3]),

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 ([4]) 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 ([5]) (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 ([6]).

(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.'

([1]) OJ C 331 E, 31.12.2002, p. 61.
([2]) Opinion delivered on 27.3.2003 (not yet published in the Official Journal).
([3]) OJ C 285, 21.11.2002, p. 4.
([4]) 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).
([5]) OJ L 248, 16.9.2002, p. 1, with Corrigendum in OJ L 25, 30.1.2003, p. 43.
([6]) OJ L 145, 31.5.2001, p. 43.