



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 September 2010
EMA/MB/528780/2010

Revision of the Financial Regulation and its Implementing Rules

Management Board meeting 7 October 2010

Background note

Following the revision of the Framework Financial Regulation (FFR) in 2008 (EC, EURATOM) No 2343/2002¹, in December 2008 the Agency presented to the Board a revised Financial Regulation applicable to the Budget of the European Medicines Agency, which was provisionally adopted pending the approval by the Commission.

In accordance with Article 99 of the Agency's Financial Regulation (EMA/MB/359871/2007), 'the management board shall also, as far as necessary and with the Commission's prior consent, adopt detailed rules for implementing the financial regulation, on a proposal from the Director.

Matters for consideration

1. Revision of the Financial Regulation

In March 2009, the Commission confirmed that the Agency's Financial Regulation does not depart from the FFR and that the revised document can be submitted to the management board for final adoption, provided that a number of editorial comments are taken into account (BUDG D1/AM/D(2009)1594 – Annex I). The Agency had also enquired about a deviation from Article 16 to maintain its surplus as a reserve for budgetary fluctuations, to which the Commission had not agreed. The Agency tried to continue the discussion with DG Budget with very limited success. Therefore now all comments made by the Commission have been fully taken into account and the version of the Financial Regulation, provisionally adopted by the Board on 11 December 2008, has been changed accordingly (Annex II).

2. Revision of the 'detailed rules for implementing the financial regulation' (Implementing Rules)

The Agency's Implementing Rules were fully reviewed in 2004 with some amendments in 2005 and 2006. Following the revision of the FFR in 2008, the Agency has completely overhauled the implementing rules, which are now closely based in content and form on the General Implementing Rules (applicable to the general budget of the European Union). A few adaptations were made in order

¹ Amended by Commission Regulation (EC, EURATOM) No 652/2008



to make the rules more relevant to the operations of the Agency and to create a document that is both understandable and practical in the day-to-day use for the Agency's staff (Annex III).

In accordance with Article 99 of the Agency's Financial Regulation the Commission was consulted on the draft rules and preliminary prior consent was obtained by email confirmation. The official letter from the Director General of DG Budget is expected in due time.