



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 August 2012
EMA/269255/2012

Decision on setting up an advisory committee on procurements and contracts (ACPC)

The Executive Director

Having regard to Council Regulation No 726/2004, and in particular article 64 thereof,

Having regard to the Financial Regulation of the European Medicines Agency ("the Agency"), and in particular article 74 thereof,

Having regard to the Implementation Rules of certain provisions of the aforesaid Financial Regulation, and in particular article 77 thereof,

Whereas the decision of 1 January 2010 setting up an Advisory Committee on Procurement and Contracts ("ACPC") should be modified,

Has decided

Article 1 – Structure of members of the ACPC

An Advisory Committee on Procurements and Contracts is hereby set up to examine procurement contracts prior to signature on behalf of the Agency.

The Chairperson and the members shall be appointed by the Deputy Executive Director.

The Chairperson shall be grade AD9 or above

The members of the ACPC shall not be delegated authorising officers for procurement related expenditure and shall be:

- Representatives of the Legal Service
- Representatives from the Finance and Budget Sector
- Representatives from other sectors who have experience in procurement related matters

The ACPC may avail itself of the advice of external experts, which will have no voting rights.

The organisation of the ACPC secretariat is the responsibility of the Chairperson.

Members of the Contracts and Procurement service shall attend meetings in a non-voting capacity to point out foreseeable difficulties as regards compatibility with the provisions applicable and the principle of sound financial management.



Article 2 – Scope of the ACPC

1. The ACPC shall give its opinion, in an advisory capacity, on:
 - a) the compliance with the Financial Regulation and its Implementing Rules regarding procurement and contracts;
 - b) all applications for a negotiated procedure over €60,000 in value prior to the procedure being launched by the responsible Authorising Officer;
 - c) All proposed contracts and specific contracts for works, supplies or services involving amounts exceeding €130,000 and on proposed purchases of immovable property, irrespective of the amount involved;
 - d) Any proposed agreement supplementary to the contracts referred to in paragraphs (b) + (c), irrespective of the amount involved which would raise the total amount involved in a contract already concluded to an amount above the limits;
 - e) The standard texts for invitations to tender, particularly the general terms and conditions, or any texts departing appreciably for such standard texts;
 - f) Questions arising at the time of conclusion or in the course of performance of contracts (e.g. cancellation of orders, requests for remission of penalties for delay, departures from the specifications and general conditions of contract), should the matter be sufficiently serious to justify a request for an opinion;
 - g) At the request of the responsible Authorising Officer, proposed contracts involving an amount below the limit referred to in paragraph (b) and (c) if the contracts are considered to involve questions of principle or are of a special nature.
2. The ACPC shall:
 - a) Make recommendations with regard to the general supply policy and shall carry out, or have carried out, such investigations and studies as may be necessary;
 - b) Make recommendations defining the general conditions for procurements and contracts;
 - c) Ensure compliance with the annual procurement plan.
 - d) Receive for information a copy of signed procurement decisions of Authorising Officers prior to a tendering procedure.
3. The ACPC may examine previously concluded contracts of its choice involving amounts below the limit specified for its powers. In order to enable the ACPC to perform its tasks, the Chairperson may obtain information on all contracts concluded.
4. In exercising its functions as defined in Article 2(1), 2(2) and 2(3) above, the ACPC shall also satisfy itself that the expenses envisaged are not out of proportion to the objective sought in the contract in question and that this objective cannot be attained more cheaply.

Article 3 - Opinions

The type of opinions that the Committee can issue are:-

- a) *Favourable opinion*: The authorising officer can go ahead with the contracting procedure
- b) *Favourable opinion with reservation*: A favourable opinion is given subject to some clarification or given certain conditions.

- c) *Negative opinion*: A negative opinion is given. The authorising office (the Executive Director) has the option to follow the opinion of the committee or decide to go ahead with the contracting procedure but in the case of the latter it will have to be logged in the register of exceptions.
- d) *Opinion on hold*: The Committee cannot give an opinion and request the presenter to re-submit the dossier

Article 4 – Organisation of the ACPC

1. All proposed contracts, supplementary agreements or general files submitted to the ACPC for opinion shall be accompanied by a report written and presented by the Authorising Officer in charge of the contract or a staff member appointed for this purpose.
2. Meetings of the ACPC shall be convened by the Chairperson. Save in urgent cases, every member shall receive each file on the agenda ten working days before the meeting.
3. In cases of particular urgency, the Chairperson may seek the opinion of the members and alternates by written procedure.
4. The quorum shall be four voting members/alternates. Opinions shall be adopted by a majority of members/alternates present.
5. The Chairperson shall organise the secretarial service for the ACPC.
6. An opinion shall be given on every file. It shall be signed by the Chairperson within eight days of the meeting and shall cover whether the procedure has been properly followed, the choice of supplier and the proposed terms of the contract.

Such opinions shall be communicated to the Unit/Sector concerned without delay.

7. The secretary of the ACPC shall write a draft summary record, which shall be submitted to the ACPC for approval and signed by all members and the secretary. A copy of the approved summary record shall be published on the ACPC website.

The opinions mentioned in Article 3 shall be filed with the dossier.

8. The ACPC shall submit to the Executive Director an annual report on its activities within two months of the end of each year.

A copy of the annual ACPC report shall be sent to all members and the Court of Auditors together with copies of all minutes for the year covered by the report.

9. The ACPC shall adopt its own Rules of Procedure.
10. The Chairperson of the ACPC shall be responsible for the implementation of this Decision.

Article 5 – Final provisions

This decision shall enter into force on 1 September 2012. It shall replace the previous decision of 1 January 2012.

“Signature on File”

Guido Rasi
Executive Director