



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Report on Agency's procurement procedure and proposed improvement action plan

Management Board meeting 15 December 2011

Background note

The European Parliament on 10 May 2011 voted to postpone the discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2009 and expected "...the Governing Board swiftly to adopt an action plan to remedy the shortcomings in the procurement procedures; asks, in particular, the Agency's Executive Director, in cooperation with the IAS and the parent directorate-general (DG), to draft this action plan which shall include specific measures and a timetable for implementation". The Management Board, at its meeting on 9 June 2011, nominated representatives of a working group (Jytte Lyngvig – Danish Medicines Agency, Guido De Clercq - DG SANCO, Björn Lemmer – European Parliament, Vincenzo Salvatore - EMA secretariat) to look at how the Agency's procurement procedure operates and to propose an action plan in order to improve the procedure.

Matters for consideration

1. Areas identified for improvement

The group discussed and identified main areas of need of improvement which are:

- Planning
- Mis-use of negotiated procedures

In order to remedy on shortcomings of procurement procedures the following areas are suggested to be set up / reviewed:

- Centralised multi annual planning
- Use of negotiated procedures in exceptional circumstances
 - Register of exceptions
- Scope and composition of the Advisory committee on Procurement and contracts (ACPC) to be reviewed



2. Multi annual planning

A procedure for a multi annual planning should be centralised and be part of the work programme in order for the Agency to have a global view based on the end of contracts but also on projects in the pipeline (The list of projects planned and approved including what sort of contract will be used to complete the project).

The planning should include all the Framework Contracts with the date of expected end, the monitoring of the use of the financial envelope by units and indicate when the new procurement procedure needs to start and this should be linked to budget availability.

A centralised procedure for planning would encourage authorising officers to plan more efficiently so that the use of negotiated procedure with the justification of urgency could be minimised. The responsibility of the procurement procedure and the resulting contracts would still lie with the Heads of unit as delegated authorising officers.

This should be continuously monitored and major deviations from the agreed plan should be reported and reviewed.

3. Procurement planning and monitoring

3.1. Negotiated procedure

To ensure that direct negotiated procedure is used only as an exceptional procedure, as foreseen in the financial Regulation, the planning must be stricter. Negotiated procedures should only be used with the agreement of the Executive Director and only as an exception. It should be clearly justified according to the Financial Regulation and Implementing Rules.

The use of negotiated procedure should be reported as exceptions.

3.2. Follow up consumption of financial envelop

Flagging up when a new tender procedure has to be started.

3.3. Lessons learned

Linked to the planning preparation.

4. Register of exception

Any deviation from the multi annual plan which imply the use of a negotiated procedure should be fully justified and authorised ex ante by the Executive Director. This request should be logged in the register of exceptions once the approval has been granted by the Executive Director.

Should a procurement procedure receive a negative opinion from the advisory committee on procurement and contracts but, the authorising officer still wishes to go ahead with a contract, this should be registered as an exception.

The list of exceptions should be part of the annual report.

5. Role of the Advisory Committee on Procurement and contracts (ACPC)

5.1. Role / scope of the ACPC

5.1.1. Current situation

An Advisory Committee on Procurement and Contracts (ACPC) was set up to examine contracts concluded on behalf of the Agency.

The decision on setting up the advisory committee on procurements and Contracts (ACPC) states that its role is to give an opinion in an advisory capacity, on:

1. All proposed contracts for works, supplies or services involving amounts exceeding the thresholds laid down pursuant to article 77(2) of the Implementing Rules to the Financial Regulation and on proposed purchases of immovable property, irrespective of the amount involved;
2. Any proposed agreement supplementary to the contracts referred to in paragraph (1), irrespective of the amount involved;
3. Any proposed supplementary agreement the effect of which would be to raise the total amount involved in a contract already concluded to an amount above the limits referred to in paragraph (1);
4. The standard texts for invitations to tender, particularly the general terms and conditions, or any texts departing appreciably for such standard texts;
5. 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;
6. At the request of the authorising officer empowered to sign the contracts or of the representative of the budget department, proposed contracts involving an amount below the limit referred to in paragraph (1) if the contracts are considered to involve questions of principle or are of a special nature.

It also indicates that the ACPC:

- 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;
- Make recommendations defining the general conditions for procurements and contracts

5.1.2. Proposed scope of a procurement procedures committee

It is proposed to review the terms of reference of the committee in order to include:

Ex-ante opinions in regards to:-

1. Review of the multi annual plan and agree on the need to run a procurement procedure
2. Review of the draft technical specification, before launching the public procurement procedure, at request
3. Evaluation of the procurement procedure

Ex-post opinion to include:-

4. Follow up and monitoring of the contract.

In summary the data to be submitted to the committee would be:

- Proposal to run a Procurement procedure
- Technical Specification of the tender procedure
- Costings
- Invitation to tender notice
- Minutes of the opening committee meeting
- Minutes and report of the evaluation committee
- Suggested contract award

5.2. Opinions

The type of opinions that the committee would be giving:

Favourable opinion

The authorising officer can go ahead with the contracting procedure.

Favourable opinion with reservation

A favourable opinion is given subject to some clarification or given certain conditions.

Negative opinion

A negative opinion is given. The authorising officer (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. This should be exceptional.

Opinion on hold

The Committee cannot give an opinion and request the presenter to re-submit the dossier.

5.3. Composition of the ACPC

5.3.1. Current situation

Currently the ACPC is composed of the Heads of Unit and the Head of sector from Legal service together with their respective alternate:

- Head of Unit Administration
- Head of Sector Human Resources
- Head of Unit Veterinary Medicines and Product Data Management
- Head of Unit Information and Communications Technology
- Head of Unit Human Medicines Development and Evaluation

- Head of Unit Patient Health Protection
- Legal Adviser of the Agency

The ACPC is chaired by the Head of Unit Administration.

5.3.2. Proposed structure of the Committee

The composition of the committee needs to be reviewed so that the members are some financial and legal actors who have some expertise in the field. The representation should not be delegated authorising officers (e.g. Heads of Unit or Heads of Sector). The Committee should have a independence from the services presenting a procurement dossier.

The committee should be made of representatives from the financial sector and the legal sector; a representative from an operational unit which would have a good understanding of the procurement procedures and each would have an alternate.

6. Time table

The Management Board will be presented at its next meeting in June 2012 with the detailed implementing measures related to:

- Establishment of the new structure and scope of the Advisory Committee on Procurement and Contract
- Implementation of a multi annual procurement plan.
- Establishment of the responsibility of the above.

Recommendations to the Board