



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 September 2012
EMA/269247/2012

Rules of Procedure of the Advisory Committee on Procurements and Contracts

The Advisory Committee on Procurement and Contracts ("ACPC") of the European Medicines Agency ("the Agency")

Having regard to Article 74 of the Financial Regulation of the Agency,

Having regard to the Decision of the Executive Director setting up an Advisory Committee on Procurement and Contracts of 1 September 2012

Has adopted the present rules of procedure:

Article 1

The ACPC shall give its opinion, in an advisory capacity, on:

1. All proposed contracts and specific contracts for works, supplies or services involving amounts exceeding the values stipulated in the ACPC's own Rules of Procedure referred to in Article 7 of this Decision 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;
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 responsible Authorising Officer, proposed contracts involving an amount below the limit referred to in Article 7 if the contracts are considered to involve questions of principle or are of a special nature.

And,

7. Make recommendations defining the general conditions for procurements and contracts:



8. Assess respect of the procurement procedure following review by the Contracts and Procurement service, which has been set up for this purpose;
9. Assess compliance with the annual procurement plan.
10. 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.
11. 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 2

The ACPC shall meet when convened by its Chairperson, whereby members will be given at least two weeks advance notice, unless exceptionally, and as agreed by all members, the time of notice shall be less. If the workload so requires, the ACPC may decide on a regular schedule of annual meetings.

Article 3

The Chairperson of the ACPC shall:

- a) convene and chair the meetings;
- b) adopt the draft agenda of the meeting;
- c) sign the opinions of the ACPC and the minutes of its meetings;
- d) inform the Authorising Officers of all requests or recommendations expressed by the ACPC;
- e) decide on the recourse to the written procedure;
- f) sign the annual report to the Executive Director as required by Article 4 (8) of the latter's decision setting up the ACPC;
- g) where necessary, request from the Authorising Officers information on past contracts;
- h) propose to hear experts or other persons.

Article 4

The members of the ACPC:

- a) may request the Chairperson to convene the ACPC and to submit to its examination any matter of principle pertaining to subjects within its responsibilities;
- b) may be requested to perform a preliminary examination of files submitted to the ACPC;
- c) may propose that matters submitted for opinion to the ACPC be withdrawn from the agenda when insufficient notice is given, when they deem that the information supplied is insufficient or that the procedure followed does not conform with existing rules;
- d) shall express their opinion at the meetings or by the way of written procedure on the matters submitted to the ACPC;
- e) shall approve the draft agenda and minutes.

Article 5

In order to ensure segregation of duties and avoid conflicts of interest, where the Chairperson or any member or alternate of the ACPC may be professionally linked to a contract, they shall abstain from voting on files submitted for opinion to ACPC.

At the start of each meeting the ACPC Chairperson, members and any alternates present shall declare if they have any conflict of interests in relation to the items to be presented. The result will be recorded in the minutes of the meeting.

Article 6

The secretary of the ACPC:

- a) shall ensure the proper functioning of the secretariat and the keeping of the files of the ACPC. The latter may be consulted during office hours;
- b) shall ensure that files are numbered appropriately, i.e. either sequentially in the case of new opinions or with the number of the initial file (e.g. adding "xxx-2") in the case extension of previous opinions;
- c) shall prepare the draft agenda based on the reports received and requests of the members;
- d) shall check that all reports to be submitted to the members of the ACPC have been drawn up in accordance with Article 7.3 of the present rules and shall send them to the members and observers with the draft agenda at least ten working days before the date of the meeting unless they are urgent and prior agreement is given by the Chairperson; files not in good and due order are returned to the requesting service;
- e) shall, within five working days following the meeting, draw up the draft minutes and opinions, and submit them to the Chairperson;
- f) shall circulate the draft minutes agreed by the Chairperson to the members for approval;
- g) may sign, if so delegated by the Chairperson, in the latter's absence or in urgent cases, any notes and information to the members necessary to ensure the proper functioning of the ACPC.

Article 7

7.1 Threshold for review of files

The ACPC shall review files for all contracts and specific contracts exceeding €130,000 in value over the contract duration. It shall also review files for all contracts concluded by negotiated procedure with a value exceeding €60,000.

7.2 Review of draft reports and contracts by Contracts and Procurement team

The draft report to be submitted to the ACPC including the final draft contract should be submitted to the Contracts and Procurement Support Officer or her replacement for review at least five working days in advance of the deadline of submission to the ACPC.

All other contracts and specific contracts exceeding €5,000 in value which have not been submitted to the ACPC shall be sent to the Contracts and Procurement Support Officer for review before signature.

Where such contracts are made by simple Purchase Order without any terms and conditions attached, such review is not mandatory. Where contracts are made by Purchase Order with terms and conditions in annex the review is however mandatory.

7.3 Reports submitted to ACPC

Reports on matters to be submitted to the ACPC:

- shall be presented in two copies (signed original for the official file and signed copy for the Chairperson); an electronic copy shall be stored in the appropriate folder in DREAM as advised by the secretariat of the ACPC;
- shall be deposited with the secretariat at least ten working days before the date of the meeting.

Reports deposited at a later date will be submitted exceptionally and only if urgent, to the ACPC, who shall decide whether to examine the file or not. However, no document shall be accepted within 48 hours of the meeting.

Each report to the ACPC for a contract shall be drawn up using the standard report template prepared by the Contracts and Procurement Office and shall contain the following information:

1. title, type of contract and reference number
2. value of the contract
3. duration of the contract
4. procurement procedure followed
5. name and address of the proposed contractor
6. expected contract deliverables
7. date and signature of the responsible Authorising Officer

Annexes:

- a) copy of the signed procurement decision by the Authorising Officer, including justification for any negotiated procedure
- b) copy of the invitation to tender documents
- c) record of the opening of tenders
- d) copy of the signed evaluation committee report(s) – both invitation to tender and pre-qualification stage, if applicable
- e) copy of the successful tender
- f) final draft contract
- g) copy of the report from the Dun and Bradstreet database on economic and financial capacity
- h) any other relevant document

Each report to the ACPC for a specific contract shall be drawn up using the standard report template prepared by the Contracts and Procurement Office and shall contain the following information:

1. reference number of specific contract and framework contract, name and address of contractor
2. value of specific contract

3. duration of specific contract
4. expected specific contract deliverables
5. framework contract ceiling
6. date and signature of the responsible Authorising Officer

Annexes:

- a) Copy of the request for services from the Agency to the contractor
- b) Copy of the reply from the contractor
- c) Final draft specific contract
- d) Any other relevant document

7.4 Presentation of files at ACPC meetings

Each report shall be presented at the meeting by the staff member in charge of the contract or by a duly appointed representative. A person familiar with the subject matter may accompany this person.

Article 8

The opinions issued by the ACPC will have the format indicated in Annex 1.

Article 9

The following rules shall apply when the ACPC delivers its opinion by the way of a written procedure:

1. the recourse to the written procedure is authorised by the Chairperson, on the basis of a duly motivated request;
2. each written procedure will deal with one subject matter only;
3. the transmission note circulating the documents shall indicate the date and time of expiry of the written procedure;
4. members and observers wishing to express comments shall do so in writing, and ensure that these comments are delivered to the secretariat before the time of expiry of the written procedure;
5. comments delivered in writing shall be forwarded to the service requesting the opinion. Once the service in question has delivered its answers in writing, the Chairperson shall circulate the latter to all members and observers and shall decide whether the questions raised have the effect of suspending the written procedure. In that case the Chairperson shall fix a new expiry date for the procedure. However, in the light of the nature of the written comments received, the Chairperson may decide, on his own or at the request of a member, to postpone any decision to the next meeting of the ACPC;
6. also in the case of a written procedure, the opinion of the ACPC shall be in the format shown in Annex .

Done in London, 3 September 2012

[Signature on File]

Noel Wathion
ACPC Chair



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Annex 1

*[Favourable/with reservation/Negative/on hold] Opinion
Nr [xxx-x]*

[Meeting Nr.] ACPC [meeting/written procedure] of [Date]

ACPC Report Number: [Document Ref. Nr]

Title: [To be completed]

Requested Unit: [To be completed]

Amount: [To be completed]

Contract:

- ***Type:*** *[Supply/Service/Works & Framework/non-framework]*
- ***Legal basis:*** *[Type of procedure/Reference to implementing Rules]*
- ***Duration:*** *[To be completed]*
- ***Contractor:*** *[name and address of proposed contractor(s)]*

Remarks:

[To be completed with outcome of discussion at ACPC meeting]

Noel Wathion
Chair of the ACPC

