



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Directorate F – Consumer goods
Unit F2 - Pharmaceuticals

GUIDE FOR SUBMISSION	I. HOW TO COMPLETE THE ADMINISTRATIVE FORMS?
	II. RULES CONCERNING THE PRESENT CALL FOR PROPOSALS
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NB: DO NOT SUBMIT THE PRESENT GUIDE FOR SUBMISSION WITH THE PROPOSAL

I. HOW TO COMPLETE THE ADMINISTRATIVE FORMS?

The proposal must be **typed** and **filled-in in one of the EC languages**.

The following numbers refer to the superscript numbers indicated in the proposal submission forms (A/1 to A/5).

1. Proposal project acronym

Use a clear, self explanatory title, providing guidance as to the content of the project

2. Applicant Name

Indicate the name of the lead organisation as it appears in Form A/3.

3. P. O. Box

If applicable, indicate number of Post Office Box for mail delivery.

4. Post Code

If applicable, enter numerical (alphanumeric for United Kingdom and The Netherlands) post code without being prefixed by the country identifier, e.g. 1000 and not B-1000 or SW1H 9AS and not UK-SW1H 9AS.

5. Cedex

If applicable, indicate Cedex for mail delivery.

6. Telephone n° and Fax n°

Please indicate telephone and fax numbers in the following format, for example (a European Commission telephone number in Brussels, Belgium): (32-2) 2991111 (32 being the country code number; 2 the area code number for international calls; 2991111 the subscriber's number).

7. Planned start date

Remember that the project cannot start until the contract has been signed, which could be 2 to 3 months after the deadline for submission.

8. Organisation Legal Name

If applicable, name under which the organisation is registered in the official trade registers or any other official register.

9. Organisation short Name

Acronym in the applicant's language.

10. Legal Status

Please use one of the following codes:

- GOV:** Governmental (local, regional or national public or governmental organisations e.g. libraries, hospitals, schools);
- INO:** International Organisation (i.e. an international organisation established by national governments);
- JRC:** Joint Research Centre (i.e. the Joint Research Centre of the European Commission);
- PUC:** Public Commercial Organisation (i.e. commercial organisation established and/or owned by a public authority);
- PRC:** Private Commercial Organisation including Consultant (i.e. any commercial organisations owned by individuals either directly or by shares). Please indicate, in such case, the type of organisation (e.g.: SA, LTD, GmbH, independent person...);
- EEI:** European Economic Interest Group;
- PNP:** Private Organisation, Non Profit (i.e. any privately owned non profit organisation).

11. Business Area (NACE)

Indicate the principal activity of your organisation, or, in the case of a larger organisation, of the executive division of your organisation making the proposal.

12. Financial Statement Form/ Total yearly revenues or resources

- For companies (form A/5)

Information from the most recent accounting year should be used. The figures should be given for the organisation as a whole and not just for the subsidiary company or the department carrying out the work.

Data has to be introduced only in the yellow cells. All other cells are automatically filled and protected (they cannot be edited).

The “organisation legal name” should correspond to the name(s) indicated in forms A/3 and A/4.

- Others (NGOs; public bodies; ...)

Please provide the Commission with the total yearly revenues/resources (forms A/3-A/4).

13. Number of employees

This part should be filled in by all participants. The figures shall comprise the legal organisation as a whole - not only for the department carrying out the work. Please indicate the number of full-time equivalent employees. (The contribution of part-time staff should be accounted as the equivalent number of full-time staff).

14. Independence

An organisation is independent if less than 25% of the capital or the voting rights is owned by one enterprise or jointly by several enterprises falling outside the definition of an SME (except public investment corporations, venture capital companies and institutional investors, provided no control is exercised either individually or jointly).

Independently of the ownership of capital or voting rights, please specify if any public authority supervises the organisation.

An SME (small and medium-sized enterprise) is defined as an entity that has less than 250 full time equivalent employees, has an annual turnover not exceeding EUR 50 million, or an annual balance sheet total not exceeding EUR 43 million, and is not controlled by 25% or more by a company which is not an SME (source: Commission recommendation 2003/361/EC by 6 May 2003, OJEC L 120, 20/05/2003).

If the organisation is not independent, please provide the legal name(s) of the organisation(s) which own(s) 25 % or more of the organisation or the name(s) of the public authority supervising the organisation.

15. Grant applications submitted (or due to be submitted) to European institutions or agencies in the current year

Applicants shall immediately inform the Commission service to which the current Grant Application is addressed of any request for funding submitted to, or approved by other Commission departments or Community Institutions AFTER the submission of the present application.

II . RULES CONCERNING THE PRESENT CALL FOR PROPOSALS

1 - DESCRIPTION OF THE PROJECT AND EXPECTED RESULTS

Proposals submitted must follow the following structure, and should be attached to form A/2 of the submission set:

A. Objectives (maximum 1 page)

Describe the objectives of the project.

B. Justification (maximum 3 pages)

Please provide the following information:

- (a) identification of perceived needs and constraints in the target groups;
- (b) list of target groups with an estimate of the anticipated number of direct and indirect beneficiaries;
- (c) reasons for the selection of the target groups and activities;
- (d) relevance of the project to the target groups;
- (e) relevance of the project to the objectives of the programme;
- (f) relevance of the project to the priorities of the programme.

C. Detailed description of activities (maximum 9 pages)

Please include a detailed description of each activity. In this respect, the detailed description of activities must not be confused with the plan of action.

D. Methodology (maximum 4 pages)

Please include a detailed description of:

- (a) methods of implementation;
- (b) reasons for the proposed methodology;
- (c) how the project intends to build on a previous project or previous activities (where applicable);
- (d) procedures for internal evaluation;
- (e) level of involvement and activity of other participants in the project;
- (f) role of each participant;
- (g) team proposed for implementation of the project (*by function: there is no need to include the names of individuals here*).

E. Duration and plan of action

Please indicate the duration of the project in months.

The indicative plan of action should not mention actual dates, but should start with “month 1”, “month 2”, etc. Applicants are advised to foresee a security margin in the proposed plan of action. The plan of action should not contain detailed descriptions of activities, but only their titles (please ensure that these match the titles listed in relevant section above).

F. Estimated impact on target groups (maximum 2 pages)

Please include information on how the project will improve a) the situation of the target groups and b) the managerial and technical capacities of the target groups or the participants (where applicable).

G. Publications and other outputs (maximum 1 page)

Please be specific and quantify outputs as much as possible.

H. Multiplier effects (maximum 1 page)

Please describe the possibilities for replication and extension of project outcomes.

I. Sustainability (maximum 3 pages)

Please distinguish between the following aspects of sustainability:

- (a) financial sustainability (*How will the activities be financed after the EC funding ends?*)
- (b) institutional sustainability (*Will structures allowing the activities to continue be in place at the end of the present project? Will there be local “ownership” of project outcomes?*)
- (c) sustainability at the policy level (where applicable) (*What will be the structural impact of the project – e.g. will it lead to improved legislation, codes of conduct, methods, etc?*)

2. FORWARD BUDGET

All grant applications must be supported by a forward budget showing all the costs and revenue that the applicant considers necessary to carry out the project. This forward budget must be presented using form “B” of this submission set (part B.1 for the costs and part B.2 for the revenue).

A project can be a series of related **operations or milestones** (study, organisation of a workshop, publication of a leaflet, etc.). **Please use one separate form “B.1” for each operation or milestone of the project for the expenditure side.** Then, group them and compose an aggregate budget for the whole project.

A project can also include different **phases or steps** (preparation, execution, follow-up, etc). The forward budget must contain sufficient details for each phase (cost of staff for each separate phase for instance, etc.).

The forward budget must:

- give an indication on the different types of human resources and their related costs (technical, administrative, etc.);
- be sufficiently detailed to allow identification, monitoring and control of the operation(s) proposed;
- be in balance, i.e. total revenue and total expenditure must be equal;
- be expressed in Euro;
- **be accompanied by the calculations and specifications used in drawing it up.**

The total amount must be expressed with maximum 2 decimals (e.g. 112.33€)

The requirement to express the budget in Euro is due to the fact that any grant awarded by the Commission will be in Euro. Applicant organisations in countries where the Euro is not national currency are asked to use the official EU exchange rates that can be found on the following website:

<http://europa.eu.int/comm/budget/inforeuro/index.cfm?fuseaction=home&SearchField=&Period=2005-5&Delim=,&Language=en>

If costs have been incurred in a currency other than the Euro, they should be converted to Euro using the official exchange rate of the month of submitting the report.

For selected projects, the final payment will be based on the final financial report at the end of the project and supporting documents.

Please note that flat rate amounts or lump sums must be avoided. The Commission reserves the right not to consider unexplained costs items in the amount granted.

REVENUE – FORM B2

The income side of the forward budget should show:

- the direct monetary contribution from the applicant and, if applicable, its contribution from its own resources (e.g. cost of personnel involved,...);
- the direct monetary contribution from any other fund providers and/or, exceptionally, other kinds of contribution (please specify, in such case and with a breakdown, the direct monetary contribution and other kinds of contribution);
- any income generated by the project (e.g. the yield from sales of publications during the operation, or the fees charged to participants attending a conference);

- the grant sought from the Commission, with a breakdown where several applications have been made to the Commission;
- the estimated bank interest (if any) generated by the grant requested over the period of implementation of the operation.

COSTS – FORM B1

In order to be eligible under this call for proposals, costs must:

- be necessary for the implementation of the action/project, be included in the estimated budget attached to the agreement, necessary and reasonable for the completion of the action/project, and consistent with the principles of sound financial management, in particular in terms of value for money and cost-effectiveness;
- be incurred during the lifetime of the action/project as defined in the agreement;
- actually be incurred by the beneficiary, be recorded in the beneficiary's accounts in accordance with the applicable accounting principles, and be declared in accordance with the requirements of the applicable tax and social legislation;
- be identifiable and verifiable and be backed up by original supporting documents.

The beneficiary's internal accounting and auditing procedures must permit direct reconciliation of the costs and revenue declared in respect of the action/project with the corresponding accounting statements and supporting documents.

Eligible direct costs:

The eligible direct costs for the action/project are those costs which, with due regard to the conditions of eligibility set out above, are identifiable as specific costs directly linked to the performance of the action and which can therefore be booked to it directly. In particular, the following direct costs are eligible, provided that they satisfy the criteria previously set out:

1. **the cost of staff assigned to the action/project**, comprising actual salaries plus social security charges and other statutory costs included in their remuneration, provided that this cost does not exceed the average rates corresponding to the usual remuneration policy of the beneficiary or, where applicable, its partners.

This cost must be actual cost incurred by the beneficiary and its partners, and staff cost of other organisations is eligible only if it is paid directly or reimbursed by the beneficiary. The amount per day will be calculated by dividing the yearly salary by 220 working days. Thus, staff working full-time will be considered for accounting purposes to be working 220 days per year, half-time staff 110 days per year.

In the framework of the present call for proposals, the costs for national civil servants working within the applicant organisation may be considered as eligible to the extent that they relate to the cost of activities which the relevant public authority would not carry out if the project concerned were not undertaken. In such cases, the cost of national civil servants paid from the public budget can be considered as part of the co-

financing provided by the applicant organisation and, where relevant, by its partner organisations. Applicants will have to add to their proposal a declaration that the permanent staff have been carrying out activities additional to its routine activities and the relevant time sheets undersigned by the staff and the immediate superior. The costs of the civil servants of any public organisation should not exceed the amount of co-financing provided by that organisation.

2. **travel and subsistence allowances for staff taking part in the action/project (for meetings, European conferences, etc.)**, provided that they are in line with the usual practices of the beneficiary or, where applicable, its partners on travel costs or do not exceed the scales approved annually by the Commission.

See: for travel inside Europe: "http://www.cc.cec/pers_admin/missions/guide_en.pdf" and for travel outside Europe: "http://ec.europa.eu/europeaid/perdiem/index_en.htm".

Travel expenses for journeys in the context of this agreement are eligible under the following conditions:

- travel by the most direct and most economic route;
- distance of at least 100 km between the place of the meeting and the normal place of work;
- travel by rail: first class;
- travel by air: economy class, unless a cheaper fare can be used (e.g. Apex);
- travel by car: reimbursed on the basis of the equivalent first class rail fare.

Flat-rate subsistence allowances cover all subsistence expenses during missions, including hotels, restaurants and local transport (taxis and/or public transport). They apply for each day of a mission at a minimum distance of 100 km from the normal place of work in the context of the project forming the subject of the grant agreement.

3. ***Purchase cost of equipment (new or second-hand), provided that*** only equipment purchased for the purposes of carrying out the action can be charged as direct costs.

These costs are eligible provided they are written off in accordance with the tax and accounting rules applicable to the applicant organisation and generally accepted for items of the same kind.

Moreover, only the portion of the equipment's depreciation corresponding to the duration of the project and the rate of actual use for the purposes of the project can be taken into account by the Commission, except where a different arrangement is justified by the nature and/or context of the equipment's use.

Items purchased prior to the action, even if they are used for the purposes of the action, cannot be considered eligible direct costs of the action (the use of existing equipment and the beneficiary's installations is partly covered via the indirect cost).

As regards depreciation policy, in choosing their depreciation rates, applicants must comply with experience and practice in their sector of activity, the general tax rules and the degree and conditions of use of the items concerned. And when the period of

depreciation has been chosen, it must be the same for any given category of goods used in similar conditions.

4. **costs of consumables and supplies**, provided that they are identifiable and assigned to the action/project;

Only the costs of those items which are directly linked to the performance of the operation, identifiable and assigned to the action shall be considered under this heading. Please note that the fact that the costs are specific to the action is key factor justifying direct cover of these costs (for ex. the costs of purchasing promotional material for the operation which the beneficiary has to promote).

5. **costs entailed by other contracts awarded by the beneficiary or its partners** for the purposes of carrying out the action/project, provided that the conditions laid down in Article II.9 of the agreement are met;

costs arising directly from requirements linked to the performance of the action/project (dissemination of information, specific evaluation of the action/project, audits, translations, reproduction, etc.), including, where applicable, the costs of any financial services (especially the cost of financial guarantees).

subcontracting costs: this heading can cover the costs of subcontracting or provision of services as part of the action. In other words, these are all other contracts that the beneficiary would have to conclude for the purposes of carrying out the action.

Where implementation of the assisted actions requires the award of procurement contracts, beneficiaries of grants shall award the contract to the tender offering best value for money, that is to say, to the tender offering the best price-quality ratio, while taking care to avoid any conflict of interests.

Where implementation of the assisted actions requires the award of a procurement contract with a value of more than EUR 60,000, the Commission may require beneficiaries to abide by special rules in addition to those referred to in the previous paragraph.

It is therefore necessary to justify the awarding of contracts, which means that flat-rate amounts are not permitted in this part of the budget.

Subcontracting is ruled by article II.9 of the grant agreement.

The Commission must be informed about subcontracting: information is to be supplied by the beneficiary either in the grant application if known in advance or by *ad hoc* means while the action is under way, in which case the Commission must then give its authorisation.

Subcontracting does not limit the responsibilities of beneficiaries

7. **Eligible indirect costs (administrative costs)** a flat-rate amount, not exceeding 7% of the eligible direct costs of the action, is eligible under indirect costs, representing the beneficiary's general administrative costs which can be regarded as chargeable to the action/project.

Indirect costs (or “overheads”) are defined as costs which are not identifiable as specific costs directly linked to performance of the action which can be booked to it direct, but which can be identified and justified by the beneficiary using his accounting system as having been incurred in connection with the eligible direct costs for the action. They may not include any eligible direct costs.

Overheads comprise costs connected with infrastructures and the general operation of the organisation such as hiring or depreciation of buildings and plant, water/gas/electricity, maintenance, insurance, supplies and petty office equipment, communication and connection costs, postage, etc. and costs connected with horizontal services such as administrative and financial management, human resources, training, legal advice, documentation, etc.

Where the beneficiary has a cost accounting system enabling him to book some of his overheads to the action in question by means of distribution keys, these costs can be covered on a real basis. Indirect costs which have to be identified and substantiated in the accounts. The applicant must provide a declaration on honour to proof the use of this system, and must indicate the proportion that he foresees to spent on overheads.

Indirect costs may not include costs entered under another budget heading.

Indirect costs are not eligible where the beneficiary already receives an operating grant from the European Commission.

9 Ineligible costs

The following costs shall not be considered eligible:

- return on capital;
- debt and debt service charges;
- provisions for losses or potential future liabilities;
- interest owed;
- doubtful debts;
- exchange losses;
- VAT, unless the beneficiary can show that he is unable to recover it;
- costs declared by the beneficiary and covered by another action or work programme receiving a Community grant,
- Excessive or reckless expenditure.
- Participation of any staff of European Institutions (attendance or speeches at conferences, seminars, etc)
- Contributions in kind

The Commission may accept co-financing in kind, if considered necessary or appropriate. In such cases the value of such contributions cannot cover all the necessary co-financing.

These are contributions provided to the applicant by a third party free of charge, such as voluntary work or the use of equipment. Contributions of real estate (such as the use of a building or of premises) are excluded. These contributions may be included in the financing plan for the action (for the same amount in part B1 and part B2) provided the costs are actually borne and entered in the accounts of the third parties who bear the costs

or that they are generally accepted on the market in question for equivalent types of service.

For further information see article II.14 of the draft grant agreement attached to the “Submission set”

3. EVALUATION AND SELECTION OF APPLICANTS AND PROJECTS/ACTIONS

All applications will be examined and assessed by an evaluation committee, set up for that purpose by the concerned department.

The assessment of each proposal will be based on the information provided by the applicants in the proposal submitted in reply to this call for proposals. In addition, the Commission reserves the right to use any other information from public or specialist sources.

All the information will be assessed in light of the **eligibility, selection and evaluation criteria** set out in the call for proposals. The eligibility, selection and evaluation procedure consists of **successive stages**. Only the proposals meeting the requirements of one stage of the assessment will pass on to the next.

At the end of the evaluation, the evaluation committee draws up a list of proposals, which may be financed, in order of merit, indicating the proposed amount to be financed by Community funds.

The conclusion of the evaluation committee is recorded in a report signed by the members of the committee and proposed to the authorising officer.

Further information concerning the evaluation

When assessing the evaluation criteria set out in the call for proposals, the evaluation committee generally pays attention to the following elements. Please note that those elements, which are indicative and non-exhaustive, are given on the basis of transparency and in order to help applicants to improve their applications.

Evaluation criteria and key elements likely to be assessed by the evaluation committee	Max. Score
1. Relevance	20
e.g. How relevant is the proposal to the objectives of the published theme? {For ad hoc grants, how relevant is the proposal to the objectives and the priorities of DG Enterprises work-programme?}	
How clearly defined and strategically chosen are the target groups?	
How relevant is the proposal to the needs of the proposed target groups?	
2. Visibility	10
To what extent will the Community involvement in the project or activity be publicised?	
3. Impact	30

e.g. To what extent is the project likely to have a tangible impact on its target groups?	
To what extent does the proposal contain potential multiplier effects? (Including possibilities for replication and extension of project outcomes, dissemination of information.)	
To what extent do the expected results of the project further DG ENTR's work-programme and main priorities.	
To what extent does the proposal contain objectively verifiable indicators for project outcomes?	
4. Quality	20
e.g. How coherent is the overall project design? (Including preparedness for evaluation.)	
How coherent, appropriate and practical are the activities proposed?	
To what extent has the project been well thought out or prepared.	
To what extent does the proposal contain specific elements of added value, such as innovative approaches, models for good practice, promotion of gender equality and equal opportunities?	
How clear and feasible is the plan of action?	
5. Budget and Cost-effectiveness	20
e.g. To what extent is the budget clear and detailed? Does the breakdown of the budget, category by category, offer a way of ensuring that the amount of the grant awarded is the minimum necessary for the operation to be completed?	
Do the probable results stand in a reasonable relationship to the amount of the grant?	
To what extent there are no better ways of achieving the expected results?	
To what extent is the proposed expenditure necessary for the implementation of the project?	
Maximum total score	100

Reminder - If a total score lower than 70 points or a score lower than 50% for any section is obtained, the proposal will not be evaluated further.

4. DECISION OF THE CONTRACTING AUTHORITY

On the basis of the list of merit drawn up by the evaluation committee, the authorising officer adopts the final list and allocates the grants.

All the applicants will be informed in writing of the Authority's decision concerning their application.

Please note that a decision to reject an application or not to award a grant will be based on the following grounds:

- the application was received after the closing date;
- the application is incomplete or otherwise non-compliant with the stated administrative conditions;
- the applicant or one or more participants are ineligible;
- the technical capacity is considered insufficient;
- the financial capacity is considered insufficient;

- the proposal has not reached the minimum score of 50% for one or several of the evaluation criteria or 70 points of the total;
- the score obtained by the proposal is not ranked amongst the best proposals considered for the award.

The Contracting Authority's decision to reject an application or not to award a grant is final.

If, at any stage of the administrative treatment of grant applications, the persons or entities concerned consider that they have been affected by an instance of maladministration, they may, irrespective of any other means of redress, make a complaint to the European Ombudsman in accordance with Article 195(1) of the EC Treaty and as provided by the Parliament Decision of 9 March 1994 on the regulations and general conditions governing the performance of the Ombudsman's duties published in Official Journal of the European Communities L 113 of 4 May 1994.

<http://www.ombudsman.europa.eu/form/en/default.htm>

II I. SUPPORTING DOCUMENTS TO BE INCLUDED WITH THE GRANT APPLICATION

CHECK-LIST FOR APPLICANTS

Before sending in the application, please check the following:

- All the sections of the **application form** (Forms A, B, C, D, E and full proposal + description) have been completed, where appropriate in accordance with the guide for submission.
- The **eligibility criteria** for the applicant and for the action / work programme laid down in the call for proposals (point 5) or equivalent have been met.
- Any rules relating to **the period for carrying out the action** mentioned in the call for proposals or equivalent have been complied with.
- The **budget** for the action / work programme has been drawn up in **euros** and is **exclusive of VAT** (failing which, reasons must be given for non-recovery of VAT), has **costs and revenue in balance** and contains a **detailed statement of all estimated eligible costs**.
- The **co-financing statement form** (C in the submission set) has been duly filled in and signed **by the applicant**
- *If applicable*, the **co-financing statement form** (C in the submission set) has been duly filled in and signed **by partner beneficiaries and third party sponsors**.
- The **grant requested complies with the ceilings** laid down in the call for proposals (point 4) or equivalent in relation to the total estimated cost of the action / work programme and/or the eligible costs proposed.
- The application has been made **within the deadline** for submitting proposals as laid down in the call for proposals (point 8) and has been **dated and signed by the authorised representative**.
- **References/qualifications** in the relevant field have been specified and/or produced.
- **The following documents have been attached to the proposal:**
 - Description and detailed **timetable** of the operation;
 - **Curriculum vitae** of persons to be performing work in connection with the operation;
 - **Legal entity form** duly filled in and signed
 - **Official registration certificate;**

- **Articles of association/Statutes;**
- **Financial identification form** duly filled in and signed
- **List of directors/executive board members** (names and forenames, titles or positions in the applicant organisation);
- Particulars of:
 - current or earlier participation in operations financed by the European Commission,
 - contracts concluded with departments of the European Commission
 - other (e.g. operations on behalf of other international organisations or Member States of the European Union)
- If applicable, declaration of honour concerning the accounting system (to book to the action real indirect costs)