

ANNEX 1

OPTIONS FOR A PROCEDURE FOR IDENTIFICATION AND DEVELOPMENT OF EUROPEAN REFERENCE NETWORKS

This document is based on contributions received from members of the working group and takes into account also existing examples of European cooperation in related fields (e.g. selection and designation of Community Reference Laboratories in the area of feed and food safety and animal health). The paper outlines options for procedure for identification and development of European reference networks (ERN) and should serve as a basis for further discussions on this topic by health ministers in the Council, but also by other stakeholders involved in this field.

1. GENERAL PRINCIPLES

The aim is to organise at European level an access to high level shared expertise in a given field for health professionals as well as patients. In principle, expertise should travel rather than patient themselves. However, it should be possible for patients to travel to centres where this is necessary.

Therefore, one of the fundamental principles of the future system of ERN is that **networking of expert centres rather than isolated European centres of reference** should be supported. This is fully reflected in this draft proposal. The proposed procedure should help identify existing EU networks and further support their activities. The concept of network should be sufficiently flexible.

However, **this mechanism should not result only in ‘passive’ identification of what already exists**. The mere fact that for some diseases EU-wide networks of expert centres do not currently exist should not result in excluding of such centres from this process. Therefore, it is also important to consider how to support efforts of such ‘independent’ centres seeking to establish or join a European reference network. These centres should be encouraged to establish EU networks with other centres active in the given field, respecting the principles and the general framework, criteria already developed in the framework of the HLG working group on centres of reference as presented in the 2005 HLG Report. This issue is dealt with in Section 3 of this Paper.

In any event, the **European reference networks should be at any time open for any new centres** which would wish to join provided that such centres fulfil all the required conditions and criteria.

Another important principle is **respecting responsibilities of the Member States** as defined by the Treaty establishing the European Community. The Member States are primarily responsible for organisation, financing and delivery of healthcare and they are therefore best placed to oversee the expert/reference centres in their territory and to keep regular contact with them. The national authorities should therefore play an active role in the process.

2. OPTIONS FOR PROCEDURE FOR IDENTIFICATION AND DEVELOPMENT OF EUROPEAN REFERENCE NETWORKS

The following options for procedure could be used in order to identify already existing EU networks, to support their development but also in order to support establishing of new networks. Whatever proposed option is chosen, the necessary standards of transparency should be ensured throughout the whole process.

2.1. OPTION 1 (Adaptation of existing mechanisms)

A first option is to adapt the existing mechanism, which is in a way being applied to pilot projects under the 2006 Call for proposals under the Public Health Programme:

- HLG working group on European reference networks, in close cooperation with the Commission, develops criteria that need to be fulfilled by the networks.
- If expert input is needed, the working group mandates an expert group (for example the Rare Disease Task Force (TFRD) for rare diseases area).
- The financial support for the networks is provided from the Public Health Programme or from the Framework Research Programme.
- The Commission publishes a call for proposals. Projects are then evaluated by the Commission, with involvement of external evaluators if needed. The successful projects are approved by the Committee of the Member States ('Programme Committee'). The Commission formally takes the final decision, publishes the list of successful projects and provides them with the financial support.
- Not all the Member States currently participate in the HLG working group on centres of reference. However, in order to safeguard transparency of the process, it is necessary to ensure that all the Member States can contribute to this process.

This option might be considered in a short term perspective and it is a valuable one until a new mechanism is set up. However, from the long-term perspective this might be difficult as: the Public Health Programme is limited in terms of budget and time, competition is tough and it does not guarantee long-term sustainability for the projects. The situation might be slightly better with the Framework Research Programme. However, this option is in fact already available and has not been widely used so far.

2.2. OPTION 2 (New specific mechanism for European reference networks)

From the long term perspective, the working group presents another option, which is to establish a new specific permanent mechanism for identification and development of ERN. This would include:

- A specific procedure of call for proposals dedicated to ERN (to be kept as simple as possible)
- An EU specific legal instrument on providing financial support to ERN.
- A Member States Committee on ERN to be in charge of the steering of the general process

2.2.1. Actors involved

Each Member State should clearly identify its **national competent authority** (for example ministry of health). These national authorities should be important points for contact with centres, for dissemination of information, for some preliminary procedural tasks in the process of identification and development of ERN and for certain supervisory tasks.

In order to ensure that the decisions are taken on the scientific and expert basis, the Commission in close cooperation with Committee of the Member States should establish **expert panels** (for example different expert panels for various diseases or specialties). The final list of experts would be approved by the Committee of Member States. A ‘Call for expression of interest’ for potential members of each Expert Panel would be published by the Commission and the selection of the experts would be based on agreed criteria. A proposal for such criteria could be developed for example in close cooperation with the HLG. Such criteria may include e.g. education, professional experience, expertise proven by publications and participation in relevant projects etc. Balanced geographical distribution should be ensured within the various Expert Panels. Participation of certain stakeholders in the Expert Panel could be also specified (e.g. at least one representative of patients, one representative of health professionals, a representative of the Commission should be part of each panel). It should be, of course, ensured that the members of the Expert Panel are free of any conflicting interests.

Finally, interests of the Member States should be represented by the **Committee of the Member States on ERN**. This Committee would be formally established, but in practice it could be simply just a transformed HLG working on centres of reference, for example. In close cooperation with the Commission, this Committee would be responsible for the definition of the general strategy for development of ERN (e.g. identification of priority areas, supervision of the procedure, assessment of the process and recommendations to the Commission on organisational and governance, legal and financial issues).

For establishing of such a new Committee, a new legal instrument would be needed (a Council decision seems to be the most suitable solution).

2.2.2. Proposed procedure

The following procedure would be used in order to identify EU networks which already exist and which are potentially ENCR:

Call for proposals

- The Commission publishes a specific call for proposals for ERN. Criteria of the call for proposals would be specified in close cooperation with the HLG working group on centres of reference (or later with the Committee of the Member States, which would replace the HLG working group).
- If a special need is detected for ERN in a specific priority area, a call for tenders may be also considered, enabling to define more precisely the priorities and criteria in the text of the call.

Mobilisation of experts

- Besides the official publication of the Call for proposals by the Commission, the national and regional authorities in close cooperation with professional and patient

representatives should also contribute to disseminating of the information about the Call for proposals directly to the potential applicants.

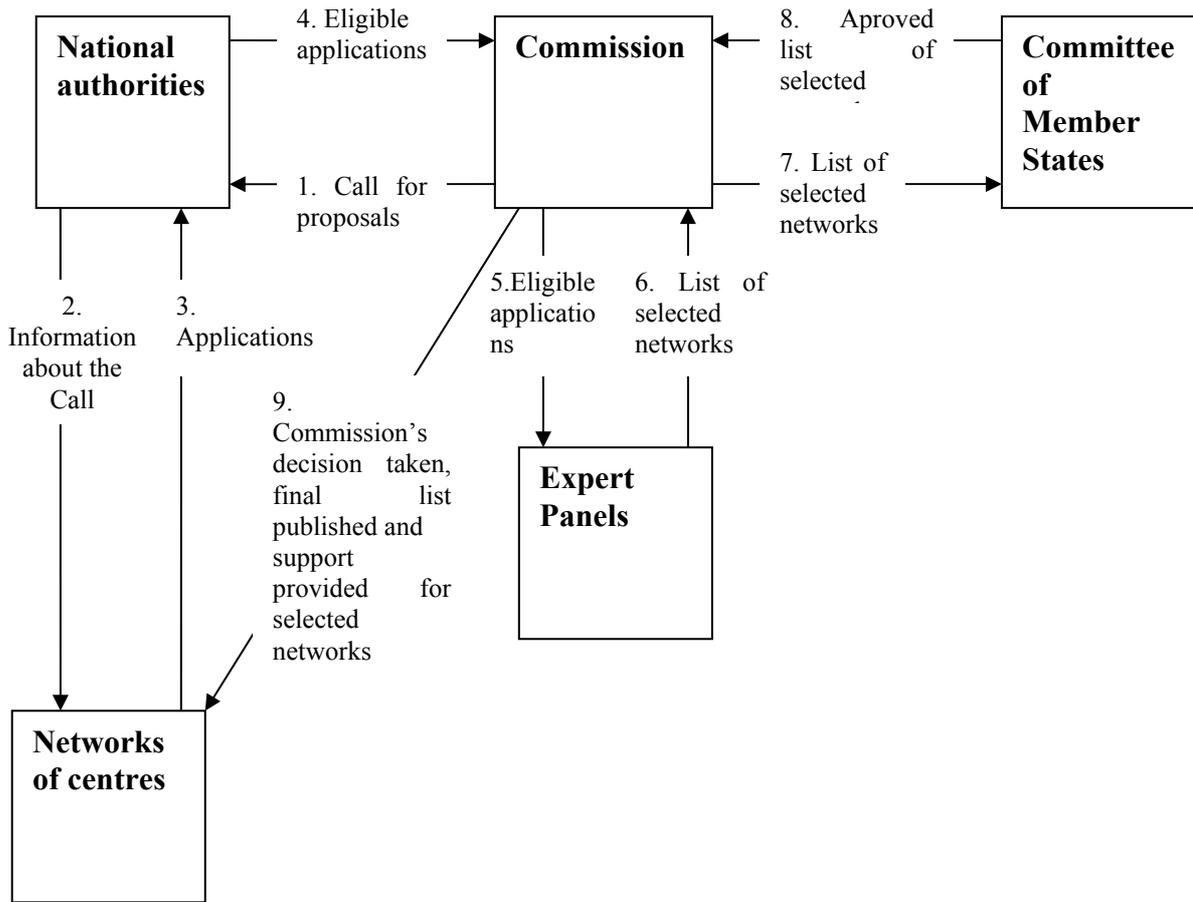
Identification of ERN

- EU networks, which are involving by definition centres from several Member States, should submit applications to the national authority responsible for the leading/coordinating centre of the network. Specific criteria to be met by leading/coordinating centres should be set up. All centres willing to join or to set up an ERN have to inform their national authorities.
- The national competent authorities conduct a preliminary check of exclusion criteria and transmit eligible applications to the Commission.
- The Commission registers applications and transmits them to the Expert panel for a given field.
- The concerned Expert panel, with secretarial support from the Commission, evaluates applications and prepares a list of selected EU networks that fulfil all required criteria. It should i.a. assess the need for the existence of a ERN on the given disease or group of diseases in a given field and an added value of the applying network. Applications should be assessed with regard to specificities of the given area or specialty.
- The list of selected ERN is then transmitted through the Commission to the Committee of the Member States. The Committee approves or amends the list of selected EU networks. The approved list goes back to the Commission.
- The Commission takes the formal final decision on the list of selected EU networks and officially publishes this list.

Support for ERN

- Subsequently, the Commission provides the selected EU networks with (financial) support for their activities, respecting all relevant financial rules. A special legal instrument on providing financial support to the European reference networks would be an option, specifying i.a. eligible costs to be funded from the EU funds.

Diagram 1.



Dissemination of information about ERN

All stakeholders, in particular national and regional authorities, organisations of health professionals, patient organisations and the European Commission should actively disseminate the information about available ERN.

Ensuring continuing compliance with criteria and evaluation

Finally, it is necessary to ensure that EU networks continue complying with agreed criteria also after they have been formally selected for the support:

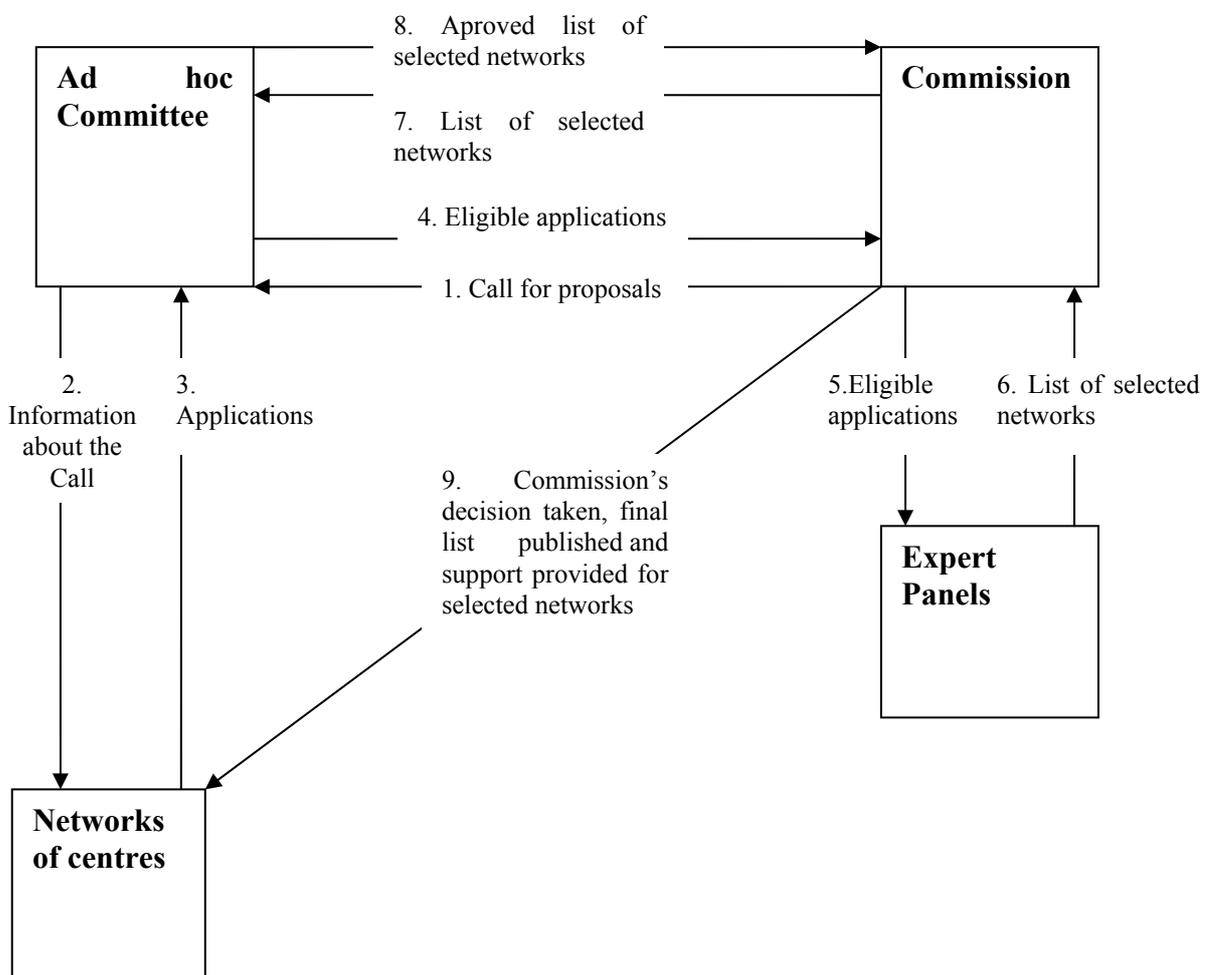
- First of all, permanent and periodic ‘self-regulation’ mechanism and evaluation should be established within networks. The networks themselves (e.g. a leading/coordinating centre) would need to make sure that all centres in the network, as well as the ERN itself comply with the criteria.
- The Commission and the Committee would have a right to re-assess the compliance with the criteria or to mandate an independent external evaluation at any time, based e.g. on repeated and founded complaints. The Commission, in close co-operation with the Committee of the Member States, would have also a right to impose sanctions if it found that the EU networks do not comply with the criteria (for example by limiting the financial support).
- In any event, network’s compliance with criteria will be systematically re-assessed after a fixed period of time (e.g. 3 years).
- As mentioned above, it should also be ensured that the networks are open to all centres which do comply with the criteria. Therefore the Commission in close co-

operation with the Committee of the Member States should also have right to examine complaints against arbitrary refusal of participation in the network.

2.3. OPTION 3 ('Concentrated procedure')

Alternatively, the Option 2 could be modified so that more tasks are concentrated within one single Committee gathering the Member States, the Commission, patient and health professionals representatives and possibly also other stakeholders. Members of this Committee would then have several tasks: to develop criteria for the call for proposals (together with the Commission), to disseminate information in the Member States, to collect the applications, to conduct a preliminary check of exclusion criteria and to first approve the list of networks selected by the Expert panels. This Committee would be administratively supported by its Secretariat.

Diagram 2.



3. 'INDEPENDENT' CENTRES WITH POTENTIAL TO CREATE A EU NETWORK OF CENTRES OF REFERENCE IN THE FUTURE

As mentioned above, the mere fact that some specialised centres do not belong to a EU network, simply because no such a network for a given disease exists at EU level, should not result in excluding them from the process of identification of European networks of

centres of reference. On the contrary, those centres should be carefully identified and subsequently encouraged to establish EU networks/ERN.

As a first step, information relating to the process of establishing European networks of centres of reference should be actively and widely disseminated (for example via the Commission's website, Member States authorities, concerned expert groups etc.) Mapping exercises (as for example the one being currently conducted by Orphanet and the RDTF for rare diseases expert centres in the 25 Member States) could also help to identify the various expert/reference centres existing in other specific fields relating to ERN.

However, as a next step a mechanism for providing more practical assistance might be also considered. One option might be to establish also a similar procedure for identification of potential leading/coordinating centres and encourage them and provide them with assistance for establishing of new ERN.

4. FINANCIAL IMPLICATIONS

From the long-term perspective, the working group recommends that a special allocation of resources from the Community budget is ensured, which is necessary for the successful implementation of the mechanism for identification and development of ERN as described. This budget allocation might be from the public health area, Research Framework Programmes or other (e.g. structural funds). Further details on providing financial support to ERN could be defined in a specific legal instrument.

OVERVIEW OF ADVANTAGES AND DISADVANTAGES OF OPTIONS FOR PROCEDURE FOR IDENTIFICATION AND DEVELOPMENT OF EUROPEAN REFERENCE NETWORKS

Options	Advantages	Disadvantages
Option 1 – Adapting of existing mechanisms	<ul style="list-style-type: none"> - does not require major structural changes - relatively easy to execute in a short-term perspective 	<ul style="list-style-type: none"> - very limited in terms of budget and time - does not guarantee long-term sustainability for the networks - does not address related practical, financial and legal issues, which are specific for ERN
Option 2 - New specific mechanism for European reference networks	<ul style="list-style-type: none"> - provides long-term sustainability for the networks - opportunity to address specific practical problems of ERN, including financial and legal issues - distribution of competences at all levels within the implementing structure is more transparent than in Option 2 	<ul style="list-style-type: none"> - requires new specific instrument, so lengthy inter-institutional negotiations - requires specific allocation of resources from the Community budget - creation of implementing structure requires more time and resources than Option 3
Option 3 - Concentrated procedure	<ul style="list-style-type: none"> - provides long-term sustainability for the networks - opportunity to address specific practical problems of ERN, including financial and legal issues - less time and resources needed for creation of implementing structure than Option 2 	<ul style="list-style-type: none"> - requires new specific instrument, so lengthy inter-institutional negotiations - requires specific allocation of resources from the Community budget - distribution of competences at all levels within the implementing structure is less transparent than in Option 2