

# **A procedure for identification and development of European Reference Networks (ERNs)**

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**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 highly specialized centres where this is necessary.**

# THE POINT STATEMENT (1)

## **Flexible definition of Centres of Reference**

Depending on size of country, disease & number of patients

## **Patient involvement in establishing, monitoring and evaluating Centres of References**

Permanent advisory committees where patients have a seat

## **Universal quality criteria should apply to national and European Centres of Reference**

## **Comprehensive and holistic approach**

This includes psycho/social aspects, diagnosis, care and treatment

## THE POINT STATEMENT (2)

Necessary **funding** has to be made available

**Equal access** for all patients, including travel funding

**Data** : collection, exchange, evaluation

**Networking** of Centres of Reference

Ensure **continuity** of services

## Other important recommendations

- Access to a second opinion if necessary (even if it implies travelling abroad)
- Experienced team
- Involvement in research
- All diagnostic tools available or accessible
- Mission of information on the RD in order to improve diagnosis
- Launch (1st prescription) of all necessary and latest therapies
- After identification of CoR, network all centres at EU level with exchange of information (within and cross-diseases)
- Permanent support by EU funds

**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.**

**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.**

**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.**

**Three main procedures have been discussed so far by the HLG Working Group on ERN. The first one is already in place, whereas the other two mechanisms are being proposed for consideration.**

## OPTION 1

- 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.

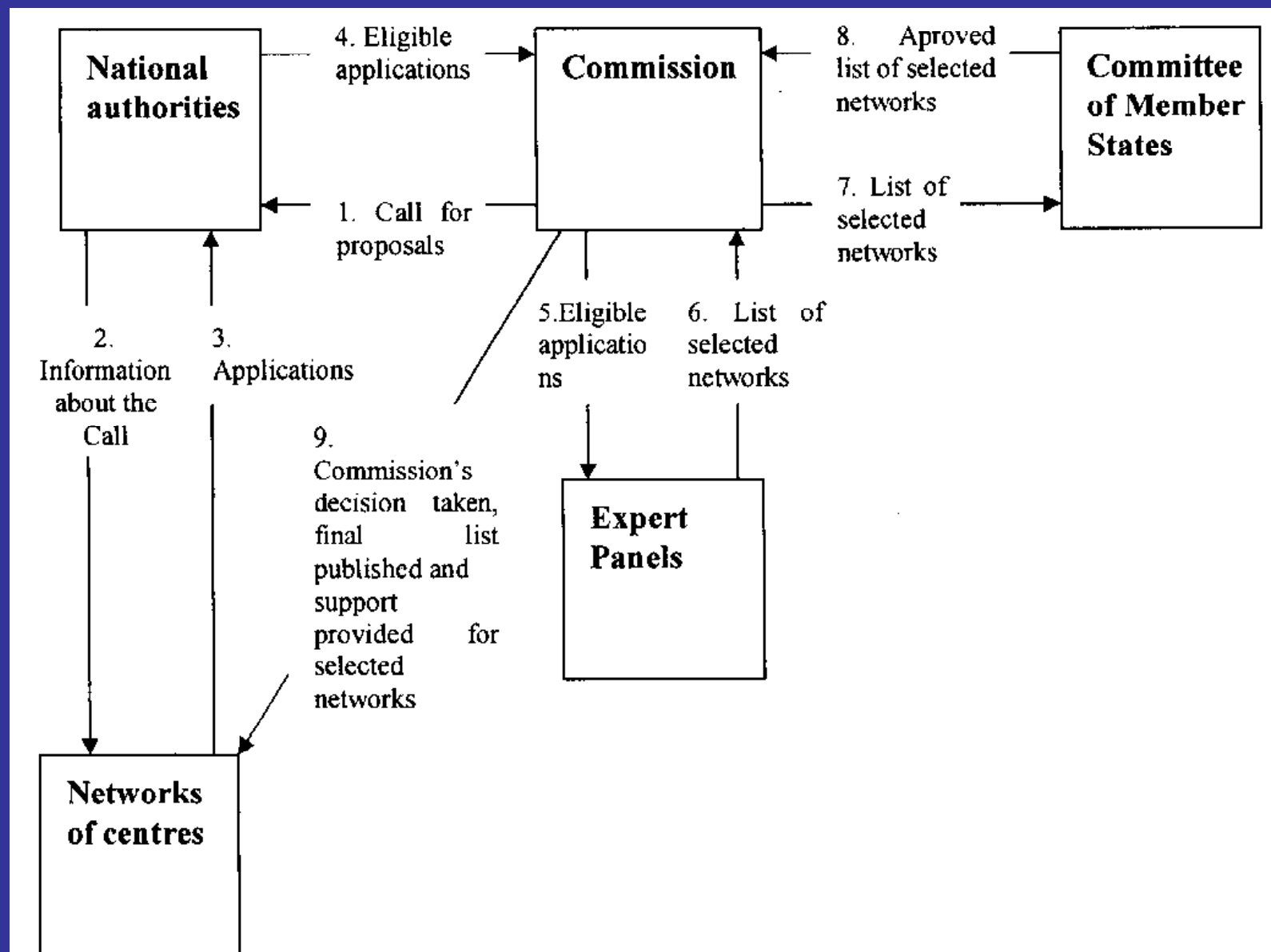
- The Commission publishes a call for proposals. Projects are then evaluated by the Commission, with involvement of external evaluators if needed. The successful projects are approved by the Committee of the Member States (“Programme Committee”). The Commission formally takes the final decision, publishes the list of successful projects and provides them with the financial support.

## **OPTION 2**

**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 proposal 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

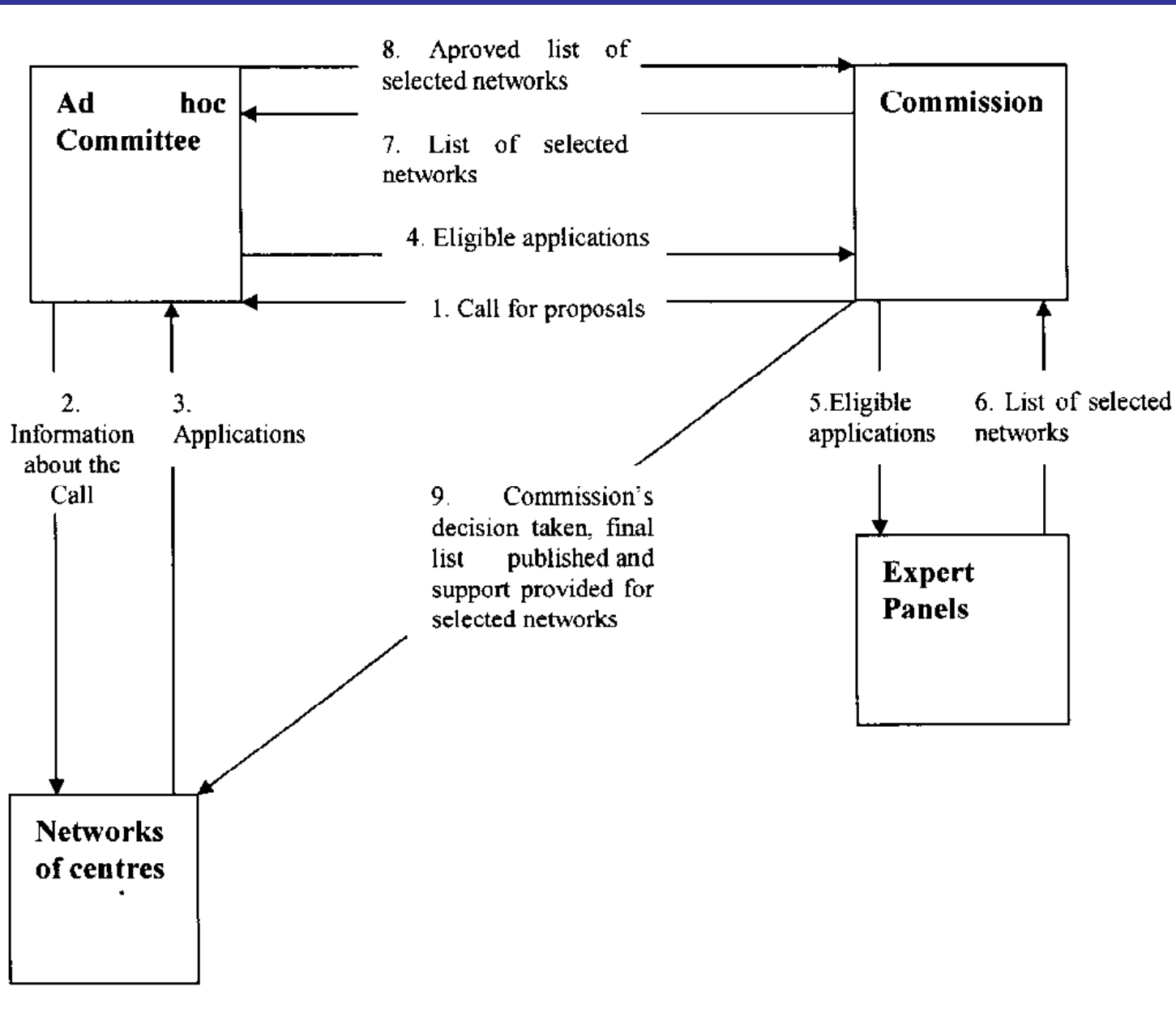
# Option2 – New specific mechanisms for European Reference Networks



## OPTION 3

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.

## Option 3 – Concentrated procedure





**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**

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 mechanisms for identification and development of ERNs 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 should be defined in a specific legal instrument.

Options	Advantages	Disadvantages
<p><b>Option1 — Adapting of existing mechanisms</b></p>	<ul style="list-style-type: none"> <li>- does not require major structural changes</li> <li>- relatively easy to execute in a short-term perspective</li> </ul>	<ul style="list-style-type: none"> <li>- very limited in terms of budget and time</li> <li>- does not guarantee long-term sustainability for the networks</li> <li>- does not address related practical, financial and legal issues, which are specific for ERN</li> </ul>

<b>Options</b>	<b>Advantages</b>	<b>Disadvantages</b>
<b>Option 2 - New specific mechanism for European reference networks</b>	<ul style="list-style-type: none"> <li>- provides long-term sustainability for the networks</li> <li>- opportunity to address specific practical problems of ERN, including financial and legal issues</li> <li>- distribution of competences at all levels within the implementing structure is more transparent than in Option 2</li> </ul>	<ul style="list-style-type: none"> <li>- requires new specific instrument, so lengthy inter-institutional negotiations</li> <li>- requires specific allocation of resources from the Community budget</li> <li>- creation of implementing structure requires more time and resources than Option 3</li> </ul>

<b>Options</b>	<b>Advantages</b>	<b>Disadvantages</b>
<b>Option3 - Concentrated procedure</b>	<ul style="list-style-type: none"> <li>- provides long-term sustainability for the networks</li> <li>- opportunity to address specific practical problems of ERN, including financial and legal issues</li> <li>- less time and resources needed for creation of implementing structure than Option 2</li> </ul>	<ul style="list-style-type: none"> <li>- requires new specific instrument, so lengthy inter-institutional negotiations</li> <li>- requires specific allocation of resources from the Community budget</li> <li>- distribution of competences at all levels within the implementing structure is less transparent than in Option 2</li> </ul>