



VASCERN

**1st Annual seminar
13-14 October 2017**

**Update of 11th meeting of the ERNs
Board of Member States
11 October 2017**



13th October 2017

Key Points

1. HCPs : procedure for the new call
 2. Affiliated Partners : Procedure for their nomination
 3. Integration of ERNs into the national health systems
- Some issues that need to be further discussed



HCPs :
Invitation process for new
HCPs to join existing ERNs



New Call for HCPs : What to do ?

Each network should :

- **Update** their specific selection criteria (that were prepared by each one in 2016)
- Prepare a **mapping document** assessing the geographical, scientific and clinical **gaps** for each network
- Define the network development **needs** (types of competences, number, territorial wish for full geographical coverage...)



HCPs call : Procedure divided in 3 steps

Step 1 : Pre assessment of the Applications by each ERN

- Production of an advisory opinion (not the end of the procedure if no favourable pre-ass as originally proposed by the board...)

Step 2 : Validation by Member States

- According to a procedure for official endorsement (as we have known it for the first call...)

Step 3 : Designation by EC according to 3 levels

- Eligibility checking of the applications by EC
- Technical assessment by Independent assessment body
- Final ERNs Board's Approval



HCPs call : 2 specific issues

- Board is judge in case of conflict between step 1 and 2
- Call not opened for Affiliated Partners at this stage



HCPs call : ERN Coordinators Group proposed a Position Paper

- **Priority for countries where ERNs not currently represented**
- Need to currently update the minimum set of criteria in each ERNs
- Need to harmonize the minimum set of criteria between all ERNs in order to precise what is a « centre of excellence »

HCPs call : EURORDIS position

- Need a **stepwise and focused approach** in the procedure of HCP's call :
« Open restricted call for new members could easily turn into the failure of ERNs »
- Need to **work closely between MS and network coordinators**
 - To have an equitable coverage of all MS in all ERNs
 - To take into account and respect the national networks on RD
 - To redefine criteria and conditions for expertise in order to provide the assurance of robustness and quality of ERNs



Affiliated Partners :

Precisions on procedure for their nomination and integration into ERNs



What is an Affiliated Partner ?

Draft position of the WG's board

2 types of AP

- Associated national centres (such as clinics, hospitals, laboratories..) → Specific criteria to the area of expertise
- National coordination hubs (institutional structures)
→ Role in coordination, information...

1 priority

- « ..Priority for affiliated partners with no full member in a given ERN... »

Reasons for termination of the affiliation

- « *The case of the integration into an ERN of a full member from the MS of origin of the AP* »
→ In this case the new full member will represent the new focal point of the MS and the Affiliated Status is over
(warning about the risk of inflation of AP ...)



Affiliated Partners : Necessity that ERNs CG be consulted...

Perspective

- ERNs CG will receive a new version of the draft at the end of november (including the comments of the board)
- As for the ERNs call, it is expected a **position paper of the ERNs CG** which will be presented by the chief of CG for the next board on December
- **Final decision** concerning the procedure of AP in December (delayed call for AP)



Integration of ERNs into the national health systems And referral of patients to the ERNs



Integration of ERNs into the national health systems and referral of patients to the ERNs (Lessons drawn from the National Survey Nov 2016)

Some issues :

- How to harmonize legal frameworks on ERNs procedure ?
- How to give legitimacy to ERNs : who gives the endorsement for an ERN ?
- How does a patient is referred to an ERN ? (does the GP have the capacity to refer to ERN.... ?)
- ...

→ **Working groups** will be created in order to exchange on national practices and find some european solutions (4 coordinators will be mandated on a voluntary basis)



Points to be clarified ...

Points to be clarified...

- **HCPs call :**
 - Risk (or not) of having different set of criteria between ERNs for the pre-ass step ?
 - Need to connect the new HCPs call procedure and the French endorsement for the new national reference centres (certified in August 2017...)
- Need to clarify and improve the **coordination** between Board, ERN CG and the opinion of each ERN ?
- Need to precise the referral of patients to the ERNs
→ **THE objective of the ERNs Network !**



**Many thanks for your
attention !**



ERN Working Group (Coordinator) on ETHICS (conflict of interest)

➤ MAIN PRINCIPLES :

- Transparency
- Industry stakeholders cannot take place in the governance of the ERNS
- Each ERN should define its own code of conduct to manage Conflict of interest
- **! « there must be no industry funding of any operation ERN activity »**

➤ WORKING GROUP PROCESS

- This working group is **temporary**
- The draft presented during the 10th October Board has been sent to the coordinators and DG sante , and after comments , has been sent to the BoMS —Now it has to be finalised by lawyers.

- **Next step** : bigger code of conduct have to be write, not only on conflict of interests.

- **Questions** still be not answered : examples :

Who will evaluate?

Who needs to disclose? To whom will be reported (internal-external?)

What to do with the policy that HCP professionals already follow