**Applying for Participation in Rare Diseases European Reference Networks**

**Process for Health Care Providers**

**National Clinical Programme for Rare Diseases**

9 March 2016

**Directive 2011/24/EU on patients’ rights in cross border healthcare (Article 12)**

According to the legislation the Member States Competent Authority is required to provide a written statement of endorsement for their Rare Disease Health Care Provider (HCP) verifying that its participation in the proposal to establish a European Reference Network (ERN) is in accordance with its national legislation before the application is made to be assessed to join an ERN.

For the latest updates on ERNs and how to apply please refer to the following link <http://ec.europa.eu/health/ern/implementation/call/more_info_en.htm>.

Member States are responsible for:

* defining their national process to assess applicant Rare Disease Health Care Providers for entry to ERNs; and
* ensuring that this process is transparent.

In addition, it is within the competence of the Member States to define national ‘Affiliated Centres’ that may also receive a letter of endorsement from the national competent authority. ‘Affiliated Centres’ are healthcare providers and potentially laboratory providers (with INAB or EQA evaluation) that provide national expertise in rare diseases but may not have the capacity to fulfil all the criteria necessary for full membership of an ERN.

It will be within the remit of the specific ERN, when established, to describe its process to invite affiliated centres to join the ERN. It is proposed that affiliated partners will have access to services for treatment and diagnosis and opportunities to collaborate with development of guidelines, registries and research as deemed appropriate by the ERN Co-ordinating team, i.e. network proposals must describe pathways of how affiliated partners other than approved members of the network can interact, participate and contribute to the network.

**Types of Health Care Providers that participate in ERNs**

Health care providers (HCP) with expertise in rare diseases that may apply to participate in ERNs may include:

* Standalone centres that primarily provide rare disease multi-disciplinary (MDT) healthcare
* Networks of HCPs that together provide co-ordinated MDT care for patients
* Smaller HCP sites that provide some or all of the multi-disciplinary care required for the management of rare diseases care

**National Designation Process Ireland**

All HCPs wishing to apply to be put forward by Ireland for consideration for entry to ERNs must undergo an assessment process on their ability to meet specific criteria. These criteria are based on those set out by the European Union Committee on Expertise in Rare Diseases.

In Ireland there are two potential levels of ERN participation for HCPs:

* Full membership
* Affiliated membership

Applicants must choose which membership level they wish to apply for and should review the process for Full Membership in the first instance. If approved by the HSE (Acute Hospitals Division) and the Department of Health through this process, this HCP is then considered a designated national centre of expertise and can be nominated to join an ERN.

To apply for Full Membership please complete the Self-Assessment Template [insert link to template here]. Please note that there is a requirement to pass all criteria or demonstrate an improvement plan for Full Membership/National Irish Designation. Guidelines for completing the self-assessment according to the ERN EC manual can be found at <http://ec.europa.eu/health/ern/docs/amt_technicaltoolbox_en.pdf>

**Application procedure for healthcare networks**

In addition to completing the template, for healthcare networks, providers must identify in their applications:

* The nominated network co-ordinator
* The list of healthcare professionals and professional affiliations.

The network co-ordinator should organise the completion of the Self-Assessment Template for all members collectively.

**Full Membership Status**

To apply for entry to ERN HCPs must:

* Identify a designated Clinical Lead who is a consultant who must have a permanent Consultant post at the HCP
* Complete the Self-Assessment Template application form, including additional required documentation
* The completed template should have written approval by the HCP CEO/ Manager
* Submit the completed Self-Assessment Template form and written approval to the Programme Manager, National Clinical Programme for Rare Diseases, Royal College of Physicians of Ireland, Setanta House, Setanta Place, Dublin 2.

|  |
| --- |
| **Exclusion Criteria**:  HCPs already accredited to participate as full members in a recognised pilot ERN that provides MDT care prior to 31 Dec 2015 will be eligible for National Designation status for the management of those specific rare diseases if the pilot network is still funded/operational, subject to all of the following being in place:   1. The main applicant (Consultant) having a permanent position 2. A letter of endorsement/invitation from the Pilot Network Coordinator 3. The HCP will be registered on Orphanet 4. The NCPRD will review the paperwork and then send on to HSE Acute Hospitals Division for nomination.   This National Designation status will be limited to those specific diseases for which they are accredited under their pilot ERN participation. The National Designation application process will need to be completed for other rare diseases they wish to include. |

The Acute Hospitals Division, supported by the National Clinical Programme for Rare Diseases (NCPRD), will consider applications for Full Membership that appear to meet all the criteria and may make a recommendation to the Department of Health for National Designation for consideration by EC to participate in a relevant ERN. The call for 2015-2016 is now closed but HCPs may join an ERN at any time after the ERN is established.

The process for evaluation of ERNs, Coordinators and Member State HCPs is now available at the following link: <http://ec.europa.eu/health/ern/implementation/call/more_info_en.htm>.

**Affiliated Membership**

The majority of HCPs with rare disease expertise in Ireland will not meet all the criteria set out in the Self-Assessment Template and, therefore, will be ineligible for full National Designation. They may, however, apply for Affiliated Membership.

Affiliated Membership status may be awarded based on meeting less stringent criteria than Full Membership. HCPs should indicate which status they are applying for on their application form.

To apply for Affiliated Membership status, HCPs must

* Identify a designated clinical lead who is a consultant in a permanent role with the service.
* Complete registration as an expert centre on Orphanet via the online registration system at <http://www.orpha.net/consor/cgi-bin/index.php>.

**Orphanet: European Rare Diseases Portal**

All rare disease health care providers, regardless of membership status, will be required to maintain an up to date registration of their clinical centre of expertise on Orphanet (<http://www.orpha.net/consor/cgi-bin/index.php>), including the completion of the Orphanet Quality questionnaire describing their multidisciplinary expertise in rare disease management. Assistance with registration is available through Orphanet Ireland (01 809 7448 or [orphanet.ireland@mater.ie](mailto:orphanet.ireland@mater.ie) )