EURO-NMD patient representatives Constitution and Rules of Procedure

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Table of Contents

Common Specifications and Definitions

Introduction

European Reference Networks (ERNs) have been established on the **founding principle of patient empowerment and involvement**[1], to improve access, safety and quality of diagnosis, care and treatment for people living with a rare or complex condition, or who require highly specialist interventions that call for the centralisation of cases, expertise and resources[2]. Patient representatives are experts by experience and their participation in ERNs is recognised as integral to represent patients' needs and perspectives in network discussions and activities, and ultimately to support ERNs delivery on their goals.

The EUCERD ERN Recommendations and Addendum[3], formally recognised the critical and integral role that patient representatives play as formal members of the decision and opinion making structures of ERNs. As experts by experience, rare disease patients draw on their knowledge of living with a rare disease, enhancing the expertise in clinical services and research networks, building a critical mass of knowledge to tackle the EU rare disease public health priority.

Preamble

To organise and coordinate patient involvement in the EURO-NMD ERN, this document sets out:

a. The function and remit of the patient representatives and the criteria that they must fulfil to join the Patient Advisory Board or a Specialist Group **(Part 1 - Founding Principles and Membership)** and;
b. The process for governing the Patient Advisory Board, and the recruitment process of patient representatives **(Part 2 - Rules of Procedure)**;

[1] OJ L 174, 17.5.2014, p. 71, Commission Delegated Decision 2014/286/EU of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil, Annex 1(2b)

[2] OJ L 174, 17.5.2014, p. 71, Commission Delegated Decision 2014/286/EU of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil

[3] European Union Committee of Experts for Rare Diseases Addendum: Rare Disease European Reference Networks (2015)

Part 1: Founding Principles & Membership

1. Introduction

1.1. Patient representatives and organisations are recognised by the European Commission Expert Group for Rare Disease, as integral to the strategic and operational delivery of European Reference Networks in rare diseases (RD ERN) and should play an active role in the networks' decision and opinion-making structures[4].

1.2. Patient involvement into the EURO-NMD ERN is organised at two levels:

- Membership in the Patient Advisory Board,
- Participation in Specialist Groups (namely Specialist Disease Groups, Cross-Cutting Specialist Groups, and Advisory Boards).

2. Patient Advisory Board

i. Function and Remit of the Patient Advisory Board

2.1. The Patient Advisory Board (PAB) aims to represent the voice of patients within EURO-NMD to ensure the needs of people living with a rare neuromuscular disease are included in the strategic and operational delivery of the network. The PAB creates a bridge between the ERN and the rare neuromuscular patient community, to ultimately ensure that EURO-NMD services can answer to the needs and expectations of rare neuromuscular disease patients and therefore improve access to high quality diagnosis, care and treatment.

2.2. In order to ensure true and equitable representation of the patient voice in EURO-NMD, the PAB:

- Coordinates the participation of all patient representatives in the Network,
- Liaises with its affiliated patient organisations.

2.3. The PAB works together with the HCPs members of EURO-NMD and undertakes the following activities inside the EURO-NMD governance structure:

- Playing a central role in the development of clinical and specialised social services guidelines and outcome measures, ensuring these instruments meet patient needs,
- Contributing to the development of information for patients: treatment policies, good practice guidelines and care pathways to ensure they are patient centred by reflecting and meeting the needs of patients,
- Participating to the development of a monitoring process of the outcomes of the ERN. They will ensure feedback based on patient experience and evaluate EURO-NMD performance by reviewing quality indicators and making recommendations,

[4] European Union Committee of Experts for Rare Diseases Addendum: Rare Disease European Reference Networks (2015)

- Supporting the network in the dissemination of information and communication to the wider patient community,
- Developing educational materials for patients and families and healthcare professionals and participate in teaching activities,
- Contributing to the development of research priorities and ensure that they are informed by the needs of patients and families, and that patients are embedded in the research activities of the network,
- Providing advice on ethical issues on the application of personal data protection rules, compliance of informed consent and handling of complaints,
- Engaging with the appropriate patient communities for disease specific activities and projects,
- Improving the transparency of the provision of information (i.e. information released by EURO-NMD) while maintaining patient data privacy where required.

ii. Membership of the Patient Advisory Board

2.4. The PAB is composed of a maximum of 10 members all being involved in a patient organisation in relation with neuromuscular diseases.

2.5. The PAB consists of two types of members:

- Elected EURORDIS ePAG representatives. In 2016, EURORDIS in collaboration with the European rare disease community established 24 European Patient Advocacy Groups (ePAGs) as forums to optimise the involvement of patient representatives of the rare disease community in the 24 ERNs. These groups are composed by appointed patient advocates, some of which were elected in 2016 and others have been co-opted.
- Patient representatives from invited associations. Associations can be invited if necessary to ensure a proper representation of the neuromuscular patient community among the PAB. Representatives from invited associations are appointed either by the PAB or the Executive Committee of EURO-NMD.

2.6. All PAB representatives are based in the European Union. PAB members are, as far as possible, from different countries to ensure a balanced geographical representation.

2.7. To the extent possible, PAB members represent affiliated patient organisations dedicated to different neuromuscular pathologies, to ensure the widest representation possible of the neuromuscular patient community.

2.8. PAB membership is voluntary.

2.9. All patient representatives wishing to be involved in EURO-NMD must have, knowledge of rare neuromuscular diseases or experience of living with a rare neuromuscular disease.

2.10. PAB members are not remunerated for their role in the Patient Advisory Board.

2.11. Elected and appointed members of the PAB serve for a term of the duration of the EURO-NMD project.

2.12. While operating as a collective group, no distinction will be made between patient representatives (elected or invited) or invited groups in terms of voting rights or board responsibilities. It is intended that all composite individuals within the PAB are considered to be equal.

2.13. Decisions are taken by consensus, but vote is possible if necessary. In case of equality, the voice of the Chair is predominant.

2.14. The PAB meets at least bi-monthly by conference or video conference call. The meeting dates are decided on a case by case basis. The meetings are held in English. Formal reports are issued after each conference.

2.15. PAB members must declare any potential Conflict of Interest in formal meetings or activities and remain independent, irrespective of their personal situation, pathology, association, and/or pharmaceutical industries.

2.16. In order to provide quality recommendations and feedback that genuinely reflects patients viewpoints, PAB members commit to:

- Participate actively in the work of the PAB,
- Attend, as far as possible, all PAB meetings either in person or via teleconference,
- Inform the PAB when representing the PAB at a conference, workshop, or any meeting of public importance,
- Conduct proper internal consultation with their respective member organisations to the best of their ability,
- Share important news and send a brief report of any EURO-NMD meeting attended to their respective members.

2.17. Alternate can be named in order to punctually represent a PAB member. PAB members must accept the designation of an alternate through a formal decision. An alternate must fulfil the same conditions as a full PAB member and either come from the same country, the same patient organisation or representing the same disease field.

2.18. PAB members are duly expected to be committed into EURO-NMD activities and play an active role in the ERN.

2.19. In the case of unjustified inactivity of a PAB member (no participation to the conference calls, to the face meeting, absence of emails), the PAB will consult with said inactive member to discuss his/her continued involvement in the PAB. If the situation so requires, the PAB can take the decision to exclude this member.

iii. Patient Advisory Board and Governance Structure of the ERN

2.20. Patients have to be properly represented in all the Boards and Committees of the Network.

2.21. All members of the PAB are full members of the Network Board and are full voting members of the Network Board, Executive Committee and Specialist Groups.

2.22. To ensure proper representation in all Board and Committees, the PAB also nominates, among its members:

- 1 chair representing the PAB in the **Executive Committee**. The Chair of the PAB is a full member of the Executive Committee.
- 1 co-chair thematic representatives for **Research** and **Education**
- 1 co-chair representing the PAB in **each disease specific groups**: Muscle diseases, Neuromuscular Junction Defects, Peripheral Neuropathies, Motor Neuron Disorders and Mitochondrial diseases.
- 1 thematic representative for the **Ethics committee,** who will be the chair of this committee.

These representatives are nominated by a majority vote for a mandate of the duration of the EURO-NMD project.

2.23. Additionally, the PAB endorses additional patient representatives to join Specialist Groups based on their expertise to the targeted thematic group.

3. Specialist Groups

i. Function and remit of the Specialist Groups

3.1. In this document, Specialist Groups are understood to include: Specialist Disease Groups (5), Cross-Cutting Specialist Groups (4), Ethics Committee, Education Board, and the Research Board.

3.2. The five sub-thematic areas of EURO-NMD constitute the five Specialist Disease Groups: Muscle Diseases, Peripheral Nerve Diseases, Neuromuscular Junction Defects, Mitochondrial Diseases and Motor Neuron Disease. The four Cross-cutting Specialist Groups, i.e. the Diagnostic Tools Groups cover the areas of Neuromuscular Imaging, Neurophysiology, Neuropathology and Genetics. These groups address highly specialised interventions required for the diagnosis of NMD patients.

3.3. Specialist Groups provide strategic advice and recommendations to the Network Board via the Executive Committee.

3.4. Patient representatives in Specialist Groups help to ensure that the activities of Specialist Groups reflect the actual needs of patients.

3.5. Specific activities for each Specialist Group as well as Board and Executive Committee will be regularly reported by the groups themselves and presented to the EURO-NMD PAB for information or agreement.

ii. Membership of Specialist Groups

3.6. The PAB endorses patient representatives for each of the Specialist Groups to ensure coverage of patient representation in all groups. At least one patient representative will be endorsed for each Specialist Group.

3.7. Appointed patient representatives are, as a matter of principle, based in the European Union. They are, as far as possible, from different regions to ensure a balanced geographical representation.

3.8. Patient representatives from outside the European Union may join EURO-NMD as invited members. They may only become members of a Specialist Group. Patient representatives from outside the European Union may not become members of the Patient Advisory Board or any of the Governance Bodies of the EURO-NMD.

3.9. To the extent possible, patient representatives represent affiliated patient organisations dedicated to different neuromuscular pathologies, to ensure the widest representation possible of the rare neuromuscular patient community.

3.10. Membership in a Specialist Group is voluntary.

3.11. Membership in a Specialist Group is based on expertise. All patient representatives wishing to be involved in Specialist Groups must have knowledge of the Specialist Group topic or experience of living with a rare disease that is included in the scope of that Group.

3.12. Patient representatives or patient organisations who wish to be involved in one of the Specialist Group may apply for membership by contacting the Patient Advisory Board.

3.13. Appointed patient representatives serve for term of the duration of the EURO-NMD project. They may or may not already be members of the Patient Advisory Board.

3.14. Patient representatives are not remunerated for their role in the Specialist Groups.

3.15. Patient representatives must declare any potential Conflict of Interest in formal meetings or activities and remain independent, irrespective of their personal situation, pathology, and/or association and pharmaceutical industries.

3.16. Patient representatives in Specialist Groups are expected to:

- Participate actively in the work,

- Attend, as far as possible, all scheduled Specialist Group meetings either in person or via teleconference; if necessary, nominate a proxy,
- Voice patient concerns, expectations and feedback within the remit of their Specialist Group, and convey the message of the Patient Advisory Board,
- Inform the PAB of all scheduled Specialist Group meetings and send a brief report of any EURO-NMD meeting to the PAB,
- Share all relevant communications and meaningful information with the PAB in a timely manner.

Part 2: Rules of Procedure

1. Application of New Patient Representatives

1.1. Patient representatives or patient organisations who wish to be involved in the Patient Advisory Board or in one of the Specialist Group may apply for membership by contacting the Patient Advisory Board.

1.2. The eligibility criteria for patient representatives are:

- To be officially endorsed by one or more patient organisation and/or a European Federation,
- To be experienced in living with a rare neuromuscular disease or have relevant expertise on rare neuromuscular diseases,
- To agree to adhere to the set of core values and commitments set out in this document,
- Able to speak fluent English (spoken and written).

2. Process of Approval for Patient Representatives

2.1. Enrolment of new patient representatives is through a majority vote in the PAB.

2.2. Upon receiving a declaration of interest (curriculum vitae + expression of interest and motivations), the PAB includes this application to the agenda of its following PAB conference call or meeting, in order to discuss the application.

2.3. Where the PAB endorses the nomination of a new patient representative, its Chair officially informs the new representative of his or her nomination and participation to the PAB and/or Specialist Group, as applicable.

2.4. The PAB regularly informs the EURO-NMD Coordinator and EURORDIS of new nominations.

3. Time commitment

3.1. Patient representative involvement in an ERN is an important and unique opportunity to achieve a step-change in care for rare disease patients in Europe. Active involvement in an ERN requires a considerable investment in terms of time and workload for patient representatives in order to achieve meaningful benefits for our community. Patient representatives are required to commit time to their role and is estimated as at a minimum two days per month. The estimate time commitment could be significantly higher for the patient advocates involved in the PAB and sitting in the Network Board, due to the amount of workload required to deliver on their role.

4. Disputes

4.1. If a dispute arises between EURO-NMD patient representatives, they commit in good faith to try to take steps to resolve the dispute together. They may seek advice from the PAB if needed by approaching the Chair or the PAB.

4.2. If the parties cannot settle the dispute in a satisfactory way despite the support of the PAB, any of them may request EURORDIS to mediate by submitting a Request for Mediation Form. Having a dispute mediated by EURORDIS is a voluntary process. When EURORDIS receives a Request for Mediation form, a member of the EURORDIS ERN team will first contact the other party or parties involved and seek their agreement to mediate.

4.3. Confidentiality will be guaranteed in any mediation activity.

4.4. In disputes involving clinicians and patients, the EURO-NMD Coordinator and the PAB Chair can jointly mediate.

5. Resignation of patient representatives

5.1. Patient representatives can step down from their role within EURO-NMD at any time through contacting the PAB and discussing their decision.

6. Termination of role of patient representatives

6.1. Patient representative appointment in EURO-NMD comes to an end if:

- The patient representative sends a notice of temporary suspension or resignation to the PAB, or
- The PAB decides, in discussion with the EURO-NMD Coordinator, that it is in the best interests of the PAB and ERN that the representative in question should be removed.

6.2. Before the PAB takes any decision to remove someone from being a patient representative in EURO-NMD they must:

- Inform the patient representative of the reasons why it is proposed to remove them, and
- Give at least 1 month for mediation and any concerns raised to be addressed.