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# EURORDIS – Rare Diseases Europe

## By-Laws

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April 2019

# Contents

EURORDIS – Rare Diseases Europe By-Laws .....	4
1. Vision, Mission, Values & Ethics .....	4
EURORDIS' Vision .....	4
EURORDIS' Mission .....	4
EURORDIS' Organisational Statement .....	4
EURORDIS' Values .....	4
EURORDIS' Ethical principles .....	6
2. Objectives (Statutes Article 1) .....	8
EURORDIS' Headquarter & Offices .....	8
3. Membership (Statutes Articles 3 & 4) (Annex III) .....	9
Membership .....	9
Membership resignation, suspension or loss .....	10
4. Board of Directors (Statutes Article 5) (Annex IV) .....	11
Board of Directors (Statutes Article 5) .....	11
Board of Directors Meetings (Statutes Article 6) .....	12
5. Operational Entities (Statutes Article 10) (Annex V) .....	14
Councils (Annex V.a.) .....	14
Policy Committees (Annex V.b.) .....	14
Programme Committees (Annex V.c.) .....	14
Project Steering Committees (Annex V.d.) .....	15
EURORDIS Events Programme Committee (Annex V.e.) .....	15
Editorial Boards (Annex V.f.) .....	15
6. General Assembly : Agenda & Overview of EURORDIS' operations (Statutes Article 11) .....	15
Agenda .....	15
Oversight – Annual Activity Report .....	15
Annexes .....	17
Annex I – Private Resource Development Policy (ongoing revision 2019) .....	17
Annex I.a. EURORDIS Policy on Financial Support by Commercial Companies .....	17
Annex I.b. EURORDIS Guidelines & Protocol for Bilateral Meetings with Healthcare Companies .....	17
Annex I.c. EURORDIS Policy for Declaration of Interests and Confidentiality Agreements .....	17
Annex II – Human Resource Policy .....	18
Annex II.a. EURORDIS Internal Staff Rules .....	18
Annex II.b. EURORDIS Volunteer Charter .....	18
Annex III – EURORDIS Membership .....	19

Adopted by EURORDIS BoD April 2019

Annex III.a. EURORDIS Membership criteria .....	19
Annex III.b. How to become a member .....	19
<b>Annex IV – EURORDIS Board of Directors .....</b>	<b>20</b>
Annex IV.a. Board Members’ Roles & Responsibilities .....	20
Annex IV.b. General Secretary Roles & Responsibilities .....	20
Annex IV.c. President & Vice-President Roles & Responsibilities .....	20
Annex IV.d. Treasurer Roles & Responsibilities .....	20
<b>Annex V – Operational Entities .....</b>	<b>21</b>
<b>(ongoing revision in 2019) .....</b>	<b>21</b>
Annex V.a. Council Terms of References .....	21
Annex V.b. Policy Committees .....	21
Annex V.c. Programme Committees .....	21

# EURORDIS – Rare Diseases Europe By-Laws

## 1. Vision, Mission, Values & Ethics

### EURORDIS' Vision

EURORDIS' vision is to enable better lives and cures for people living with a rare disease.

### EURORDIS' Mission

EURORDIS - Rare Diseases Europe works across borders and diseases to improve the lives of people living with a rare disease.

### EURORDIS' Organisational Statement

EURORDIS - Rare Diseases Europe is a unique, non-profit alliance of over 850 rare disease patient organisations from more than 60 countries that work together to improve the lives of the 30 million people living with a rare disease in Europe.

By connecting patients, families and patient groups, as well as by bringing together all stakeholders and mobilising the rare disease community, EURORDIS strengthens the patient voice and shapes research, policies and patient services.

### EURORDIS' Values

Based on their own assessment, the Board of Directors, members, staff and volunteers adhere to a shared set of values :

As well as embracing the common European values of **democracy, mutual respect, solidarity, social justice** and **equality** EURORDIS is also guided by the following values:

- **Patients first** – EURORDIS puts patients first and endeavours to do what's right for patients and their families. In order to maintain its **legitimacy** in representing the needs, concerns and realities of its constituents, EURORDIS stays independent from all other stakeholders with an interest in rare diseases.
- **Authentic** – EURORDIS is **credible** in representing the patient voice because its positions are based on contributions from its members and a wide range of people living with a rare disease. EURORDIS' ensures that its volunteers are people who understand what it is to be affected by a rare disease.
- **Authoritative** - EURORDIS strives for excellence in all that it does and to represent the patient perspective with the **professionalism** it deserves. EURORDIS believes in building its positions on the basis of available evidence drawn both from the scientific literature and the experiences of people living with a rare disease.

Adopted by EURORDIS BoD April 2019

- **Courageous** – EURORDIS has a strong sense of integrity and is **straightforward** in representing the needs, concerns and desires of people living with a rare disease.
- **Collaborative** – EURORDIS recognises that common problems are often solved more effectively by finding synergies and promoting collective action. EURORDIS is **respectful** of the fact that many stakeholders can help improve the lives of people living with a rare disease and therefore is open to collaboration with like-minded organisations that share its vision and goals.
- **Innovative** – EURORDIS is a **visionary** organisation that is highly entrepreneurial in seeking out and implementing new ways to serve people living with a rare disease.

<b>Patients first</b> <ul style="list-style-type: none"> <li>• <b>Independent</b></li> <li>• Legitimate</li> <li>• Holistic</li> <li>• Humanistic</li> <li>• Solidarity</li> <li>• Balanced use of emotion</li> <li>• Grass roots</li> </ul>	<b>Authentic</b> <ul style="list-style-type: none"> <li>• <b>Credible</b></li> <li>• Trustworthy</li> <li>• Genuine</li> <li>• Representative</li> <li>• «Finger on the pulse»</li> </ul>	<b>Professional</b> <ul style="list-style-type: none"> <li>• <b>Authoritative</b></li> <li>• Well-informed</li> <li>• Serious</li> <li>• Evidence-based</li> <li>• Intellectual</li> <li>• Institutional</li> <li>• Purist</li> <li>• Reserved</li> </ul>
<b>Courageous</b> <ul style="list-style-type: none"> <li>• <b>Forthright</b></li> <li>• Blunt</li> <li>• Brave</li> <li>• Relentless</li> <li>• Persistent</li> <li>• Consistent</li> <li>• No «pussy footing»</li> </ul>	<b>Collaborative</b> <ul style="list-style-type: none"> <li>• <b>Respectful</b></li> <li>• Collegiate</li> <li>• Inclusive</li> <li>• Non-competitive</li> <li>• Consultative</li> <li>• Pragmatic</li> <li>• Modest</li> <li>• Humble</li> </ul>	<b>Innovative</b> <ul style="list-style-type: none"> <li>• <b>Visionary</b></li> <li>• Creative</li> <li>• «Can-do» culture</li> <li>• Open-minded</li> <li>• Pioneering</li> </ul>

## EURORDIS' Ethical principles

- EURORDIS promotes respect of social, economic, cultural, religious or philosophical belief differences in addition to differences which may result from the diseases.
- EURORDIS has an **ethos of equity and social justice** based on the recognition of the rights of each individual in terms of access to prevention, diagnosis, care, treatment, information, support and education.
- A **spirit of partnership** underpins all of EURORDIS' activities undertaken with people living with rare diseases, family members, scientists, industries, partner organisations, as well as national and European institutions or policy makers.
- **All EURORDIS' Board members, staff, volunteers** act with **honesty, integrity and openness** in all their dealings as representatives of the organisation. EURORDIS promotes a working environment that **values respect, diversity, mutual support, trust, benevolence, flexibility, fairness, commitment and integrity**. EURORDIS aims to enable each individual to **mobilise their competences and capacities** in a supportive and cooperative environment where **autonomy and personal initiatives** are encouraged as long as such initiatives fall within the framework of the strategies, priorities and processes of the organisation. All who work for or on behalf of EURORDIS understand and adhere to EURORDIS' vision, mission, values and ethics.
- EURORDIS' **Governance** is of utmost importance. EURORDIS' ethos, performance and integrity starts and ends with the governance deontology set in its statutes and by-laws as well as in its quest for good practices. The Board of Directors and the Chief Executive Officer are responsible for elaborating the vision, mission, statements, 5 year strategy, and setting the course of strategic orientations and organisation with an oversight on operations, finances and human resources. Decisions and course of actions are made with discernment and holistic view while paying attention to short term and long term interest of the mission.
- All EURORDIS' **Programs and Activities** are developed and implemented in support of the EURORDIS' vision, mission, organisational statement, 5-year strategy and values.
- EURORDIS has a **Strategy and Program Evaluation Policy**. EURORDIS performs a full revision of its strategy every 5 years following a lighter mid-term review, conducted by the Board of Directors and the Chief Executive Officer, involving, staff, volunteers, members and stakeholders. EURORDIS regularly reviews program meaningfulness and effectiveness in a process involving senior staff and the Board of Directors; it incorporates lessons learned, addresses weaknesses and mitigates risks identified. EURORDIS is committed to improving programs and organisational effectiveness over time as well as to being responsive to changes in its fields of activities so to offer optimal value to its constituencies e.g. members, patient organisations, patients & families and stakeholders.
- EURORDIS strives to be in **Legal Compliance** at all times. EURORDIS is knowledgeable of and is committed to complying with all applicable laws and regulations and to taking prompt remedial action if the conduct of individuals within the organisation deviates from such laws and regulations. EURORDIS applies the highest available Standard of Excellence from the French Association of Associations' Treasurers. EURORDIS applies the highest standard of data protection according to regulations in a meaningful and proportionate manner. EURORDIS organises, preserves and archives all important legal documents and business records in accordance with French laws.
- EURORDIS' **Financial Policy and Stewardship** is responsible. EURORDIS manages its funds responsibly, prudently and conservatively. EURORDIS applies the highest available Standard of Excellence from the French Association of Associations' Treasurers. EURORDIS spends at least 65% of its annual budget on programs in pursuance of its mission, and less than 35% in administration and fund raising. It spends an adequate amount on administrative expenses to ensure effective

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accounting systems, budget controls, fair tendering, and other expenditures critical to professional management. EURORDIS ensures that all spending practices and policies are fair, reasonable and appropriate to fulfill the mission of the organisation. All financial reports are factually accurate and complete in all material respects. EURORDIS goes beyond what is legally compulsory in its control and audit processes. EURORDIS constitutes operating reserves between 2 to 6 months of operations and doesn't accumulate operating funds excessively.

- EURORDIS' **Private Resource Development Policy (Annex I – ongoing revision in 2019)** applies the highest available standards of excellence, from the internationally recognised US National Health Council and the French Association for the Transparency of Charitable Associations. These standards are designed to ensure transparency, accountability and good public stewardship. All private resource development activities are truthful and not deceptive. The organisation doesn't enter into agreements with organisations or individuals to raise funds on a commission or percentage basis. When seeking financial or in kind support from corporates, the organisation follows the *EURORDIS Policy on Financial Support by Commercial Companies*, together with the *EURORDIS Guidelines & Protocol for Bilateral Meetings with HealthCare Companies*, and the *EURORDIS Policy for Declaration of Interests and Confidentiality Agreement*.
- EURORDIS' **Human Resource Policy (Annex II)** is responsible. EURORDIS maintains a highly qualified multi-competence, multi-lingual, multi-cultural and multi-disease representative team of staff and volunteers for the accomplishment of its mission. Staff and volunteers act responsibly, individually and collectively. EURORDIS compensates staff, and all those who may receive compensation (such as self-employed colleagues, interns) reasonably and appropriately. The *EURORDIS Staff Internal Regulations* details all ethical principles, rules and processes for staff. The *EURORDIS Volunteer's Charter* details all ethical principles, rules and processes for volunteers.
- EURORDIS' is **mindful of the Environment**. An organisation which respects nature and mankind is a place where people can work better. The Staff Internal Regulation details how to limit waste and reduce the carbon footprint. Equipment and optimal use of information and communication technology e.g. webinars, teleconferences, web-meetings are encouraged to reduce the carbon footprint of travel, and to also save time and money.
- EURORDIS is **mindful of Animals' Rights and their Protection**. When promoting research policy and strategy, adopting position papers or public statements, participating to research infrastructures or projects, EURORDIS adheres to the following principles: the animals should be used in biomedical research only when no other means of obtaining scientific sound, valid and useful results are available; the minimum number of appropriate animals required to obtain and validate results should be used; the acquisition, care and use of animals should follow the highest national and European legislations and standards as well as with the most appropriate animal welfare measures consistent with the purpose of the research; appropriate authorisation by the competent authority should be obtained; encourage research, development and use of non-animal models (e.g. computer simulation, in-silico models, in-vitro & cellular assays)
- EURORDIS has a **Policy of Openness and Disclosure**. EURORDIS provides comprehensive information to the public, the media and all stakeholders. It is responsive in a timely manner to reasonable requests for information. All information about the organisation will fully and honestly reflect the policies and practices of the organisation. Basic information such as the statutes, by-laws, annual reports, financial reports, audit reports, list of members, composition of the Board, composition of the staff, volunteers acting on behalf of the organisation, presentation of programs and main actions, public statement and position papers will be publicly available on the EURORDIS website

- EURORDIS has a **Whistleblower Policy** intended to encourage Board members, staff and volunteers to report suspected or actual incident(s) of illegal, unethical or improper events (behaviors or practices) without retribution. The Whistleblower should promptly report the suspected or actual event to the next highest or another level of management, including to an appropriate Board member. The Whistleblower can report the event with his/her identity or anonymously and shall receive no retaliation or retribution for a report that was provided in good faith – that was not done primarily with malice to damage another or the organisation. A Whistleblower who makes a report that is not done in good faith is subject to discipline, including termination of the Board or employee relationship, or other legal means to protect the reputation of EURORDIS and members of its Board and staff
- EURORDIS is **mindful of data protection and strives to comply with the EU General Data Protection Regulation (GDPR)** in all areas, initiatives, projects and programmes where this is appropriate.

## 2.Objectives (Statutes Article 1)

EURORDIS Headquarters are in Paris with Offices in Brussels and Barcelona. EURORDIS has also staff distributed across Europe such as in London, Geneva, Cologne.

### EURORDIS' Headquarter & Offices

- **EURORDIS Headquarters and Paris Office**, are located at the Rare Disease Platform, Paris. The reasons for having headquarters in Paris are a) EURORDIS is incorporated as a not-for-profit and non-governmental-organisation under French law; b) EURORDIS has always been located in Paris since its inception in 1997; c) AFM-Telethon provides an important in-kind support with long term pro-bono office space and meeting rooms as well as all annual commodities costs in the Rare Disease Platform at former Hospital Broussais, thanks to a partnership with the Paris hospital institution Assistance Publique - Hôpitaux de Paris (AP-HP); d) the Rare Disease Platform offers a unique opportunity for EURORDIS to interact with other organisations dedicated to rare diseases such as the French Alliance for Rare Diseases, the Help Line Maladies Rares Info Service, ORPHANET, IRDiRC Secretariat, French National Foundation for Research on Rare Diseases.
- **EURORDIS Brussels Office**. Offices are rented. The reasons for establishing a permanent Office in Brussels since 2003 are a) to locate the EURORDIS European & International Advocacy staff team in Brussels where the EU institutions are – EU Council, European Commission, European Parliament, Council of Regions, Economic and Social Council; b) to recruit staff with the most appropriate experience for European public affairs; c) to interact with all relevant European stakeholders; d) EURORDIS is a member of the University Foundation / Fondation Universitaire hosting academic societies and multi-stakeholder groups in the health sector, located in the European district of Brussels, to benefit a long term low rental fees office space and a privilege access at low rental fees to many hotel rooms and meeting rooms fully equipped.
- **EURORDIS Barcelona Office**. The reasons for establishing a permanent Office in Barcelona since 2010 are a) to locate the EURORDIS team for Web Communications & social media & Community building (such as RareConnect), b) to locate the team of patient engagement (in clinical trials all along the life cycle-PARADIGM; Community Advisory Boards-CABs; participation as experts in public authorities scientific advice and assessment - EMA, MOCA; European Reference Networks & Healthcare through European Patient Advocacy Groups –ePAGs; integrated social & medical care; digital health; and research through

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the research infrastructure - European Joint Programme Co-Fund and large research consortia; c) to locate the team of the Open Academy for patient training and empowerment; d) EURORDIS has a partnership with the Autonomous University of Barcelona since 2010 and with the Foundation of the Hospital Santa Creu I Sant Pau Recinte Modernista since 2015; e) Since 2016, the Foundation provides EURORDIS with a long term low rental office space within the full Pavilio San Apolonia and a privileged access at discounted rental fees meeting rooms in the Knowledge Centre in the UNESCO World Heritage Site of Sant Pau; f) The Knowledge Center at Sant Pau Art Nouveau Site is home to leading institutions in the field of health systems sustainability, health and education, and offers a unique opportunity of collaboration with leading international institutions.

EURORDIS has staff based in different major cities around Europe. As of 2019, there is staff presence in Geneva (Rare Diseases International Director), London (Senior Event Manager), Cologne (ERN & Healthcare Advisor).

EURORDIS as an agile, decentralised, grass roots, networking organisation, accepts and encourages this distributed approach to localisation of offices, branches and individual staff. A team chart, organization chart, internal rules, working procedures, communication technology and methods are in place to enable fully integrated work. This flexibility enhances EURORDIS' capacity to recruit international staff of different cultures, languages and backgrounds as well as increasing EURORDIS' capacity to retain them.

## 3. Membership (Statutes Articles 3 & 4) (Annex III)

### Membership

*EURORDIS is a membership organisation composed of full and associate members.* Further membership categories can be decided upon and added by the Board of Directors.

*Only full members have voting rights.*

Only European non-profit, non-governmental, registered patient organisations can become or remain full members of EURORDIS and must comply with the membership criteria as decided by the Board of Director. Patients Organisations who do not comply with all membership criteria can apply for associate membership.

To obtain full or associated membership, it is necessary to apply and to be approved by the Board of Directors.

Each full member designates one person to represent it at the General Assembly. Associate and other categories of members do not hold a vote. Only those full members who are up-to date with their membership fee payments can vote.

The annual membership fees are set by the General Assembly.

The membership criteria are maintained and updated by the Board of Directors.

Adopted by EURORDIS BoD April 2019

The current EURORDIS membership criteria were adopted by the EURORDIS Board in 2007, and have been regularly revised since then with the most recent revision having taken place in November 2015, taking on board comments made at the General Assembly 2015 Madrid.

#### Criteria for full membership are as follows:

##### Patient organisations:

- That are rare disease organisations according to EU prevalence criteria (5/10 000) as defined in the: EU Regulation on Orphan Medicinal Products (1999), Commission Communication on Rare Diseases 2008), Council Recommendation on an Action on Rare Diseases (2009), and Directive on Patients' Rights in Cross-Border HealthCare (2011)
- From a European country (48 countries as defined by EURORDIS based on definitions by the EU, the Council of Europe and the WHO-Europe)
- With governing boards made up of a majority of rare disease patients or of family members of patients
- That are financially independent, particularly from the pharmaceutical industry (max. 50% of funding from several companies)
- Holding non-profit status (are non-profit and non governmental)
- With proven activities such as patient support and/or advocacy activities and/or research
- Patient organisation that have been recently (less than 1 year) created are invited to apply for "full membership", but will qualify for a provisional status as "associate member" After one year or more, their membership status can be revised by the board of directors, upon examination of their first annual report or other documents provided to show activities& proof of compliance with the membership rules

*One, or all, of these criteria could be waived in exceptional cases, due to the particularity of patient-driven organisations and of rare diseases, as well as for historical or contextual reasons; in exceptional circumstances, the funding criteria can be waived based on the Board's individual assessment of the independence and structure of funding in addition to the track record of activity and the reputation of the applicant patient organisation. In all cases, the Board of Directors makes the final decision regarding membership, and is not obliged to disclose the reasons of this internal decision, which are recorded in the minutes.*

##### Associate membership

Rare disease organisations from countries outside of Europe or those exclusively dedicated to diseases with a higher prevalence than 5/10 000 can become **associate members**.

##### Membership fees

Full membership fees are based on the organisation's annual budget (previous year). Associate membership fees are independent of your organisation's budget.

Membership fees are annual and renewed every January. The amounts of the fees are decided by the General Assembly.

Fee waivers can be considered on a case by case basis and members are encouraged to inform EURORDIS if they are undergoing any financial difficulties.

## Membership resignation, suspension or loss

Membership in the Association may be ended by the following:

- a written letter of resignation addressed to the President of the Board,
- legal liquidation proceedings or dissolution, or relevant evidence that the organisation is

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- no longer active
- dismissal by the Board of Directors in case of non-payment of dues,
- dismissal by the Board of Directors for gross breach of other Membership duties or any action likely to bring the Association into disrepute, after the member involved has previously been asked to provide an explanation.

Membership in EURORDIS may be suspended by the following:

- suspension by the Board of Directors for gross breach of other Membership duties or any action likely to bring the Association into disrepute. The member involved will be contacted and asked to provide an explanation after which, the Board may decide on ending or continuing the suspension or terminating the membership of said member.

## 4. Board of Directors (Statutes Article 5) (Annex IV)

### Board of Directors (Statutes Article 5)

*EURORDIS is managed by the Board of Directors.*

*The number of directors is at least 6 and not more than 18.*

The established practice at EURORDIS is a number of **12 directors**.

*This number is decided for the coming year by the Board of Directors; members are informed through the call for candidates to the Board; report is made to the Annual General Assembly when announcing the results of elections to the Board.*

*As a third of the Board of Directors is to be renewed by election every year, the potential numbers of directors are 6, 9, 12, 15 and 18.*

EURORDIS policy is to encourage a Board composed of directors from different countries, from different diseases, of patients or parents or engaged volunteers, with adequate competences to execute their mission as a Board member, with a track record of national or European experience. Fluency in English and high attendance of meetings are requirements. EURORDIS' policy is to also encourage diversity within the Board, including consideration of age, gender, social and professional background, culture and geographic distribution across Europe.

Collaborative team spirit and active participation between meetings are strong expectations. Board members work in the best collective interest of EURORDIS and its members, not in their respective interest of disease or country or patient organisation of origin.

EURORDIS' policy is to empower the Board in order to provide strategic guidance and control. To this end, maintaining a Board team with a good spirit of collective work and long-term view are as important as to bringing in new views. Therefore, the Board encourages a composition that mixes experienced EURORDIS Board members with new Board members, with a reasonable retainment and slow turn over.

Identification of **competing interests** and prevention of **potential conflicts of interest** are performed through the following steps: a) each candidate to the Board as well as each Board member, every year, fills in the EURORDIS Declaration of Competing Interest mostly based on the EMA one, b) these declarations are reviewed collegially by the CEO, the Deputy to the CEO, and the Financial Director, c) clearance or issues are discussed with the concerned

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Board member and the President, d) annually, the Auditors perform a Special Report on regulated Agreements ("Statutory Auditor's Special Report on Regulated Agreements").

## Board of Directors Meetings (Statutes Article 6)

*EURORDIS Board of Directors meets at least once every six months.*

The established practice at EURORDIS is to hold **4 Board of Directors meetings per year**. Usually, the Board of Directors holds 3 full meetings of 2 days each and 1 short meeting at the time of the Annual General Assembly.

The Board of Directors works by **consensus**. When **votes** are needed, votes are decided by simple majority; in the case of tied votes, the president casts the deciding vote.

The Board of Directors has an **advanced notice of meetings** at least one month in advance (practice is usually more than 6 months in advance), and the draft meeting agenda 10 days in advance. For Board of Officers meeting, the draft meeting agenda may be provided 5 days in advance. Documents to inform agenda item discussions are provided within the two weeks preceding a Board meeting.

**All agenda, minutes, documents are fully and permanently available** to Board members.

The Board of Directors **Meeting Agenda** is composed of 3 sections: Introduction, Information, Action.

Introduction covers:

- Review and approval of the agenda;
- Information on Board members;
- Adoption of Minutes of previous meeting;
- Adoption of Table of Action & Decisions from Board of Officers Meetings;
- Review of the Tracking Table of Actions & Decisions from previous meetings of the Board of Directors and Board of Officers.

Information covers:

- Finance: Presentation of monthly cash flow, quarterly revised annual budget, year-end forecast; Presentation on financial performance; Control over financial operations and administrative policy or procedures on finance and administration;
- Human Resources: Presentation of all changes in team chart, staff organisation with regards to mission and main tasks, recruitments, resignations or contract ending, job evolutions; Control and decision over new job position being created and policy or procedures on human resource, including salary, benefits and compensation policy.
- CEO report on advocacy matters, planning and programming of activities, implementation of previous Board's strategic discussions, update on projects, report on fund raising policy and activities;
- President's report on CEO performance review, compensation and discharge at least once every two years

Action covers:

- Membership applications, membership re-assessment, membership analysis
- Preparation of Annual General Assembly: agenda, documents, resolutions
- 5-year Strategy and Strategic Review every 2 / 3 years, based on an assessment of its implementation

Adopted by EURORDIS BoD April 2019

- Annual Work Programme composed of Annual Action Plan, Annual Budget, Governance and Team Charts, based on an assessment of the implementation in the previous year, evaluating the operations and program effectiveness
- Adoption of other administrative or financial or legal policies affecting public accountability
- Annual Reports composed of Annual Activity Report, Annual Financial Report, Annual Audited Financial Statements and Auditors' Report
- Strategic discussions on main advocacy issues, on new programmes or activities or events, and in-depth reporting to control their implementation
- Strategic discussions on operational entities, their term of references, their composition, their activities
- Strategic discussion on resource development, major initiatives, fund raising policies and practices
- Adoption of Position Papers, Concept Papers, Statements
- Adoption of job descriptions of main staff persons (eg Chief Executive, deputy to the Chief Executive, Chief Operating officer, Chief Finance Officer) and select the Chief Executive Officer
- Selection of candidates submitted to official calls for candidates and appointment of permanent EURORDIS representatives in external entities
- Establishing operational entities for the purpose of assisting and providing advice in the context of EURORDIS specific activities, programmes or projects

## Role of the Board of Directors (Statutes Article 7) and Board of Officers (Statutes Article 5 & 9)

*The Board of Directors retains extensive powers to make, in the name of EURORDIS, all decisions which are not exclusively reserved to the General Assembly.*

The **Board of Directors** focuses on achieving the objectives of EURORDIS for people living with rare diseases: the strategy, main programmes, overall organisation of members or volunteer entities as well as of staff and financial sustainability.

The **Board of Officers** assists the President in the implementation of decisions or orientations of the Board of Directors. The Board of Officers approve membership applications, adopt the job descriptions of new job positions, go into further details than the Board of Directors on financial matters, human resource matters, procedures, appointment of representatives or nomination of candidates.

EURORDIS Board of Directors establishes **Ad Hoc Working Groups** to work on specific topics or matters, for a short duration, with a specific deliverable, in order to prepare a Board of Directors or Board of Officers discussion or decision. Examples include but are not limited to: membership criteria; re-assessment of membership; revision of statutes; drafting of by-laws; 5-year strategic plan; establishment of a specific entity and drafting of Terms of Reference. Board Ad Hoc Working Groups are composed of some board members, CEO and staff members, according to the topic.

Members of the Board of Directors are involved in EURORDIS' activities in several ways:

- They prepare an agenda item or a strategic discussion with the relevant staff member
- They are members of some Council or Committees or Board or Groups
- All are members of the European Public Affairs Committee (EPAC)

## Role and responsibilities of the members of the Board of Directors (Statutes Article 5)

Adopted by EURORDIS BoD April 2019

*The roles and responsibilities of the Board of Directors and of the Officers are detailed in the by-laws.*

The following Roles & responsibilities are adopted by the Board, revised regularly, disseminated when calling for candidates to the Board, and tabled at each first Board meeting following the election at the General Assembly:

- Board members' Roles & Responsibilities
- President's Roles & Responsibilities
- Vice President's Roles & Responsibilities
- Treasurer's Roles & Responsibilities
- General Secretary's Roles & Responsibilities

## 5. Operational Entities (Statutes Article 10) (Annex V)

In order to help the Board of Directors to fulfill its mission, EURORDIS' management will rely on several operational entities.

For the purpose of assisting and providing advice in the context of each specific activities, programmes or projects of the association, the Board of Directors establishes the following operational entities, organized in six categories. Their creation is adopted by the Board with a Mandate & Terms of References including their objectives, composition, governance and organisation. The most important entities become part of these by-laws.

### Councils (Annex V.a.)

- The Council of National Alliances (CNA) (Annex)
- The Council of Disease Specific European Federations or Networks (CEF) (Annex)

### Policy Committees (Annex V.b.)

- The European Public Affairs Committee & EURORDIS Spokespersons (EPAC)
- The European Patient Advocacy Groups for each grouping of rare diseases (ePAGs), linked to European Reference Networks
- The Therapeutic Action Group (TAG), linked to EMA and EUnetHTA
- The Social Policy Action Group (SPAG)
- The Drug Information Transparency and Access Task Force (DITA-TF)
- The HTA Task Force (HTA-TF)

### Programme Committees (Annex V.c.)

- RareConnect
- RareBarometer
- Open Academy
- Community Advisory Boards (CABs)

Adopted by EURORDIS BoD April 2019

## Project Steering Committees (Annex V.d.)

EURORDIS sets up and/or is implicated in Steering Committees for all projects it is implicated in.

## EURORDIS Events Programme Committee (Annex V.e.)

- European Conference on Rare Diseases and Orphan Products (ECRD)
- EURORDIS Membership Meeting
- Round Table of Company Multi-stakeholder Symposium
- EURORDIS Awards
- Black Pearl Dinner

## Editorial Boards (Annex V.f.)

- Rare Disease Day
- Website
- eNews

# 6. General Assembly : Agenda & Overview of EURORDIS' operations (Statutes Article 11)

## Agenda

The established practice at EURORDIS is an Agenda covering:

- President Opening & Highlights of Annual Activity Report
- Treasurer Report & Financial Report
- Report from the Auditors on Account Auditing and Financial report
- Special Report from the Auditors on Regulated Agreements ("Statutory Auditor's Special Report on Regulated Agreements").
- Annual Work Program, including Action Plan, Governance Chart and Team Chart & Budget
- One or several topics for discussion without votes
- Presentation of candidates to the Board of Directors
- Presentation of Resolutions submitted to members' vote

## Oversight – Annual Activity Report

EURORDIS prepares an annual activity report to the members, volunteers, partners, and the public which includes:

- Statement from the President of the Board and the Chief Executive
- The 5 Year Strategy
- The highlights of achievements -for the previous year
- The Annual Activity Report as an account of activities and accomplishments - for the previous year
- The Revenues and Expenses – for the past year

Adopted by EURORDIS BoD April 2019

- The Board of Directors members and Officers – as before AGM
- The full list of Full and Associate Members – as for the past year
- The full list of conferences and events attended by EURORDIS
- The Governance Chart
- The Team Chart – with names
- The Annual Work Program for the next year –Action Plan, Budget, Charts

EURORDIS also prepares a Financial Report to the members, volunteers, partners, and the public. The report includes a Treasurer' statement, assets & liabilities, revenues & expenses, annexes with detailed explanations on main items, and the report of the Auditors. The report is reviewed by the Auditors in its entirety.

The activity report, action plan and financial report are presented at the General Assembly and are voted on by EURORDIS' full members present.



# Annexes

## Annex I – Private Resource Development Policy (ongoing revision 2019)

Annex I.a. EURORDIS Policy on Financial Support by Commercial Companies

Annex I.b. EURORDIS Guidelines & Protocol for Bilateral Meetings with Healthcare Companies

Annex I.c. EURORDIS Policy for Declaration of Interests and Confidentiality Agreements

Adopted by EURORDIS BoD April 2019

# Annex II – Human Resource Policy

Annex II.a. EURORDIS Internal Staff Rules

Annex II.b. EURORDIS Volunteer Charter

Adopted by EURORDIS BoD April 2019

# Annex III – EURORDIS Membership

Annex III.a. EURORDIS Membership criteria

Annex III.b. How to become a member

Adopted by EURORDIS BoD April 2019

# Annex IV – EURORDIS Board of Directors

Annex IV.a. Board Members' Roles & Responsibilities

Annex IV.b. General Secretary Roles & Responsibilities

Annex IV.c. President & Vice-President Roles & Responsibilities

Annex IV.d. Treasurer Roles & Responsibilities

# Annex V – Operational Entities

## (ongoing revision in 2019)

### Annex V.a. Council Terms of References

- CNA Terms of Reference
- CNA Common Goals & Mutual Commitments + Strategic Plan for Fulfillment
- CEF Terms of Reference

### Annex V.b. Policy Committees

- EPAC Rules of Procedure
- ePAG Constitution (ongoing revision in 2019)
- TAG
- SPAG Terms of Reference
- DITA – TF Terms of Reference
- HTA TF Terms of Reference

### Annex V.c. Programme Committees

- RareConnect
- RareBarometer

# INTERNAL REGULATIONS



- ❖ Preamble
- ❖ Ethos and working conditions
  - ❖ Salary and benefits
  - ❖ Employee right of expression
  - ❖ Penalties and right to defence
  - ❖ Health and Safety
- ❖ Entry into force and amendments

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*Registered office: Paris*

*Siret no.: 41345906600028*

# INTERNAL REGULATIONS

## CONTENTS

	PAGE NO.
<b>1 PREAMBLE</b>	<b>2</b>
1-1 Object and scope	2
1-2 Public interest mission	2
1-3 Strategies	2
1-4 Common values	2
1-5 Working attitude and regulations	3
1-6 Sustainable development	3
<b>2 ETHOS AND WORKING CONDITIONS</b>	<b>3</b>
2-1 Use of internet/telephone access	3
2-2 Protection of confidential information	5
2-3 Combating abuse of authority/sexual and moral harassment (COMPULSORY)	6
2-4 Zero tolerance approach to discrimination (COMPULSORY)	6
2-5 Access and working hours (COMPULSORY)	6
2-6 Lateness and absence	7
2-7 Entitlement to leave	7
2-8 Professional travel	7
<b>3 SALARY AND BENEFITS</b>	<b>8</b>
3-1 Salary	8
3-2 Mutual insurance	8
3-3 Transport allowance	8
3-4 Restaurant vouchers	8
3-5 Gift vouchers	8
3-6 Entitlement to training	8
3-7 Well-being, welcome and friendliness	9
<b>4 EMPLOYEE RIGHT OF EXPRESSION</b>	<b>9</b>
4-1 The role of staff delegates (COMPULSORY)	9
4-2 Direct and collective right of expression	9
<b>5 PENALTIES AND RIGHT OF DEFENCE (COMPULSORY)</b>	<b>10</b>
5-1 Scope	10
5-2 Scale of penalties	10
5-3 Disciplinary procedure	10
<b>6 HEALTH AND SAFETY (COMPULSORY)</b>	<b>10</b>
6-1 Health and hygiene	10
6-2 Prevention and safety	10
<b>7 ENTRY INTO FORCE AND AMENDMENTS (COMPULSORY)</b>	<b>11</b>
7-1 Effective date	11
7-2 Subsequent amendments	11

# INTERNAL REGULATIONS

## ❖ ARTICLE 1 PREAMBLE

### Article 1-1 Object and scope

This code shall be applicable to all employees of EURORDIS, to all employees on secondment, to volunteers, and to temporary workers and trainees within the organisation chart whether or not working in the framework of an employment contract hereinafter designated as “EURORDIS personnel”. Articles marked by a ° only concern employees on the payroll.

Outlined herein are the regulations applicable to issues of social law, health and safety, ethics and professional conduct.

It shall be important for each individual to consult the background, mission, strategy, annual reports and team composition of the organisation at the website: [www.eurordis.org](http://www.eurordis.org). All activities undertaken by employees, volunteers, temporary workers and trainees shall fall within the framework hereof.

### Article 1-2 Public interest mission

The mission of EURORDIS is to build a strong pan-European community of patient organisations and people living with rare diseases, to be their voice at the European level, and – directly or indirectly – to fight against the impact of rare diseases on their lives.

### Article 1-3 Strategies

EURORDIS acts on behalf of its members with the purpose of:

- Assisting patient organisations and people living with rare diseases by contributing towards the consolidation of their knowledge and skills;
- Raising awareness of the public and of national and international associations about rare diseases;
- Improving access to information, treatment, care, and support for people living with rare diseases;
- Encouraging good practices;
- Promoting scientific and clinical rare disease research;
- Developing rare disease treatments and orphan drugs;
- Improving quality of life through patient support, social, welfare and educational services.

### Article 1-4 Common values

EURORDIS expresses the voice of people living with rare diseases around key common values:

- Unity in activities and **solidarity** between employees, directors and volunteers;
- A **professional** commitment to work effectively and transparently with a requirement of achieving results and remaining individually and collectively responsible;
- A spirit of partnership underpins all activities undertaken with people living with rare diseases, family members, scientists, industries, partner organisations, as well as national and European policies;
- Mutual **respect** of social and cultural differences in addition to differences which may result from the disease;
- An ethos of **equity and social justice** based on the recognition of the rights of each individual in terms of having access to prevention, diagnosis, care, treatment, information, support and education.

Ref: staff/board workshop 2009 survey, strategy 10/15+worksheet of development of values/MM13/14 March2009)



# INTERNAL REGULATIONS

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## Article 1-5 Working attitude and regulations

Working for EURORDIS is a means of professional accomplishment due to the international reach of its activities and their political dimension.

However, more important than technical skills, the personal and professional involvement of each individual towards patients and family members is the driving force of EURORDIS.

Giving such meaning to each activity is essential, whether in terms of making requests to the highest political levels, assessments requiring a high level of scientific knowledge or the simplest and most discrete activities.

EURORDIS aims to build an environment of trust and flexibility which will enable each individual to mobilise their skills in a supportive and cooperative environment where independence and personal initiatives are encouraged, where such initiatives fall within the framework of the strategies and priority areas for activities.

Aside for some particular instances, management shall be more participative than coercive, favouring self-reliance and responsibility. It goes without saying that adopting a respectful attitude towards fellow colleagues, behaving in a courteous manner, being punctual and adopting a positive and open-minded attitude, as far as practically possible, fulfil the multicultural and altruistic character of the association.

In addition to informal occasions which lead to the possibility of interaction with management, EURORDIS has implemented a framework where each individual can express themselves via a staff delegate during monthly staff delegate meetings (4-1) or collegially in the framework of information meetings (4-2).

## Article 1-6 Sustainable development

A location which respects nature and mankind is a place where people can work better.

If each individual, within the office, makes the effort to manage waste and to respect the commitment to sustainable development, the association as a whole shall benefit, in terms of both environmental respect and upholding values in the workplace.

Waste generated within our offices above all concerns paper. The first measure to be taken consists of only printing documents when absolutely necessary, and ideally on both sides of the paper. Avoid printing in colour, and when designing documents to be printed, avoid using large areas of colour which use significant volumes of ink.

On a different note, it is preferable to use a non-disposable cup for drinks rather than the disposable kind, even if they are made of cardboard.

Additionally, try to think about measures to save electricity, even if it is not charged to us. As a matter of course, try not to leave office lights on during lunch times or periods of absence in excess of one hour.

Finally, we encourage the use of webinars, teleconferences, etc. which, as well as leading to time and cost savings, enable unnecessary travel to be avoided when possible.



## ARTICLE 2 ETHOS AND WORKING CONDITIONS

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### Article 2-1 Use of internet/telephone access

EURORDIS provides access for the “EURORDIS personnel” to the internet, an email account, a network storage location and to telephones without any restrictions or control being placed on usage.

# INTERNAL REGULATIONS

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## **Good practices for saving professional documents**

Prior to outlining the limitations on using this tool for personal use, it is preferable to outline some good practices for storing professional documents on the server.

It is always necessary to remember that (1) documents must be accessible by others, (2) it is necessary to ensure continuity in service, notably by filing documents on the server as created, with understandable file names and following logical file management rules, (3) only leave draft versions of documents on the server when necessary and ensure to tidy up file space when a definitive version of documents is created.

## **Good practices when using professional tools for personal use**

Whilst the primary and essential purpose of these tools is for professional use, it is additionally possible to use these for personal and practical purposes (e.g. to reserve a concert ticket during the daytime for a concert the same evening, to call a company which only operates during normal working hours, etc.) insofar as this use is reasonable and permitted.

### **Reasonable nature**

#### *Reasonable use of internet*

Personal use of the internet must not be to the detriment of the overall quality of work. In general, chat tools, social networks, personal blogs, etc. may lead to misuse. These are not prohibited per se but they should be used with moderation and only when absolutely essential. EURORDIS is a small team which harbours ambitious objectives: improving the life of 30 million people living with rare diseases throughout Europe. Any employee with time to spare on other activities during working hours, shall be considered as someone who is under-employed or has motivational problems. In such instances, a meeting shall be arranged with line management or with general management to resolve issues at hand.

#### *Reasonable use of telephone*

Personal calls should only be made when necessary and only to numbers within a geographical area which will not lead to any unnecessary additional expense for EURORDIS.

#### *Reasonable use of email accounts*

Insofar as these days it is very simple for everyone to open a free personal email account (gmail, msn) with large storage capacity, please try to avoid using professional email accounts for personal use. Under exceptional circumstances, an employee may be forced to suddenly stop working, making it necessary to allow another employee access to their email account. Giving access to personal details in this instance is very burdensome. Additionally avoid receiving any large files into your professional email account: storage costs money.

#### *Reasonable use of the data server*

There are several locations where data can be stored:

Q:\ Drive which everyone can access to read and write files;

U:\ Drive where individual user data is stored ("My Documents" folder);

Each user has read/write access to an account and all users have read only access to all accounts;

Aside for the "private" sub-folder located within the "My Documents" folder, where only the particular user can access their data.

As a general rule, in the same manner as with emails, it is preferable to avoid storing personal data on the server. If, due to necessity, any user needs to store personal data on the server, this should be undertaken in the user's personal account, in the "private" folder.

For technical administrative reasons, and out of a concern for continuity of service, all information stored on professional media (emails, server) shall be accessible by the employer without the need to receive prior consent from the user or for the user to be informed.

Under ordinary circumstances, out of respect for the work undertaken by each individual and out of courtesy, a user shall be informed if it is necessary to access their emails/data in case of their absence. It is uniquely in instances of

## INTERNAL REGULATIONS

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force majeure and emergency (accident, unforeseen circumstances) that the employer would access data belonging to an employee without informing the latter in advance.

### Identification of personal data stored on professional media

In order to avoid any confusion, all personal data stored on a server, computer or in an email account belonging to EURORDIS should be indicated as such. In this instance, this should be indicated, for emails, with the tag “PRIVATE AND CONFIDENTIAL” in capital letters appearing in the email subject, and for files or folders, appearing in the filename.

In such an instance, the employer or any other representative shall only access said data in the presence of the user.

### Permitted information

It shall be strictly prohibited to undertake any activities which breach human rights such as incitement to xenophobia or restricting individual freedoms on political, religious or moral grounds. The notion of intellectual property must additionally be respected and it shall be strictly prohibited to use “peer to peer” software (or any similar software type) to exchange data which is not acquired with full respect of the Hadopi Law.

The employer shall by default be held liable for all internet-related activities undertaken using its connection. For this purpose, EURORDIS shall keep records of all connections undertaken during the two previous months.

These connections shall fall within the liability of the employer, and the latter shall require no authorisation or formality to gain access thereto.

Under normal circumstances, these connections shall not be evaluated. If it appears necessary, the employer or any representative may use this data and an evaluation thereof after having informed the user(s) who operate the computer(s) which are the object of the investigation.

### **Article 2-2 Protection of confidential data**

In the framework of their duties,

- All employees are entitled to have access to confidential data concerning health or any other domain concerning personal details of their interlocutors,
- EURORDIS representatives at the EMA have access to strictly confidential information,
- Network administrators are entitled to access professional data which is not intended to be shared with all parties, or to personal data which has not been identified as provided for under article 2-2 of these regulations.

Under all circumstances, each individual shall be bound to strictly respect professional secrecy. Any breach of professional secrecy shall be considered as a case of misconduct and may be penalised.

It is not only important to take care in protecting one’s own data, but to additionally assist other colleagues in doing likewise. If, for instance, a person sees any document to which they should not have access, even if this does not directly concern said party or if said party is not responsible for this, as soon as becoming aware, the party shall become jointly responsible. Said party should then take necessary measures to inform colleagues and ensure that such a situation does not reoccur.

The objective is not to denounce any negligence, but to act collectively and in a responsible manner when confronted with any risk which could be prejudicial for EURORDIS.

This is additionally valid for Windows session passwords and email access passwords. These codes should remain strictly confidential. They provide access to the EURORDIS network which includes extremely confidential information which each individual must protect. They must under no circumstances whatsoever be informed to other colleagues. Only computer service providers and management have access codes. These are the parties to inform in such instance as it is necessary for any other colleague to access any account other than their own.

## INTERNAL REGULATIONS

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If despite this prohibition, in any instance of force majeure, passwords are communicated, the computer service provider must be informed immediately so that said passwords can be changed as soon as possible.

Similarly, the password associated with a “Eurordis” user (providing access to the server on all workstations) must not be communicated to any people who are not members of EURORDIS personnel, and this should not be broadcast aloud in the workplace corridors nor written on any document. Out of the same concern for mutual protection, a friendly warning should be issued to any colleague who may be negligent in this respect.

Any obvious breach of this regulation may place EURORDIS at risk and could be the object of a penalty.

### Article 2-3 Combating abuse of authority/sexual and moral harassment

#### *Sexual harassment*

Pursuant to the provisions of the French Employment Code applicable in such instances, no employee or applicant for employment as part of a placement or training programme may be penalised or be the object of discrimination for having suffered or refused to be subject to harassment by any persons whose intention it is to obtain sexual favours for themselves or others.

No employee may be penalised, dismissed or the object of discrimination for having witnessed harassment as described in the paragraph above or for having informed others thereof.

However, any employee who in the performance of their duties undertakes such harassment shall be subject to disciplinary measures which can lead to gross misconduct.

#### *Moral harassment*

Pursuant to the French Employment Code, no employee may suffer repeated acts of moral harassment which are intended to degrade the employment conditions or to harm the rights and dignity of said employee, or alter the physical or mental health thereof, or compromise their professional future prospects.

Moreover, no employee may be penalised, dismissed or subject to any disciplinary measures, whether direct or indirect, for having witnessed harassment as described in the paragraph above or for having informed others thereof.

However, any employee who in the performance of their duties undertakes such harassment shall be subject to disciplinary measures which can lead to gross misconduct.

### Article 2-4 Zero tolerance approach to discrimination (COMPULSORY)

The purpose of this code is to set the highest possible standards in terms of a zero tolerance approach to discrimination. Particular emphasis is placed on discrimination based on sex, race, colour, ethnic origin or social background, genetic characteristics, language, religion, age or sexual orientation, wealth, birth, disability, in addition, generally speaking, to the manner in which people choose to lead their private lives.

### Article 2-5 Access and working hours (COMPULSORY):

Personnel shall only have access to the premises of the association for the performance of their employment contract, with the exception of respecting trade union responsibilities or staff delegate responsibilities.

All persons working for the association shall receive an access badge strictly for personal use which should be returned at the time of leaving employment.

Working hours are as follows:

Monday to Thursday	from 9am/9.30am to 6pm/6.30pm
Friday	from 9am/9.30am to 5pm/5.30pm with one hour for lunch.

Depending on their duties, some employees may be forced to travel on a regular basis, whilst others, for purely personal reasons, may be forced to modify their working hours for increased flexibility, finally others may receive “seasonal” workloads. Whilst the actual number of contractual hours is not an objective, but merely a means to an end, it remains nevertheless a contractual framework which should be respected aside for the consent of the direct line manager.

## INTERNAL REGULATIONS

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EURORDIS aims to offer the maximum amount of flexibility as possible in terms of working hours as far as practically possible so as to place an emphasis on the personal involvement and professional awareness of each employee.

The latter point shall only be pertinent in a favourable context. Direct line managers shall oversee that such flexibility does not lead to laxity and does not detriment the equal distribution of work within any single team.

### Article 2-6 Lateness and absence (COMPULSORY)

Any lateness should be informed and justified to one's line manager who shall subsequently inform the personnel department.

Repeated instances of unjustified lateness may lead to a penalty for which due provision is made under article 5 of these regulations.

Absence due to illness or accident should be justified within 48 hours by the issue of a medical note indicating the likely duration of absence, aside for any instance of force majeure.

Any absence other than that for illness or accident must be justified within a maximum of 3 days, aside for any instance of force majeure.

Any unjustified absence in these conditions may lead to a penalty. The same shall be applicable for any unauthorised or unwarranted early departure from the workplace, aside for those persons who are required to regularly be absent in the framework of their duties.

### Article 2-7 Entitlement to leave

#### *Holiday leave°*

The duration of leave shall be 25 days per annum.

EURORDIS entitles those employees who so wish to benefit from 5 or 10 additional days of annual leave. This provision shall lead to an equivalent reduction in salary. Salaries are calculated on the basis of full-time employment, namely the total number of days worked on the legal basis of 25 days of leave per annum.

Aside for any derogation, leave must be spread over at least two individual periods, by rotation between employees so as to ensure the smooth running of the association.

As a derogation, annual leave acquired may be taken in the month immediately following the month of acquisition (each employee acquires 25 days/12 months = 2.08 days per month).

#### *Public holidays and non-working days*

In total, there are 11 public holidays and non-working days: 1 January, 1 May, 8 May, 14 July, 15 August, 1 November, 11 November and 25 December, Easter Monday, Ascension Thursday, and Whit Monday.

### Article 2-8 Professional travel

Certain roles may require travel outside of the workplace.

Each user, through their professional email account, has a personal calendar and it is possible to share common calendars between people. Each instance of travel away from the workplace should be indicated as soon as practically possible in the calendar so it is possible to know where each employee is at any time.

A posteriori, instances of travel away from the workplace shall be declared on the attendance form.

In the framework of travel away from the workplace, travel expenses shall be reimbursed in full insofar as these expenses correspond to the framework for which provision is made by the procedure. For meals, employees shall not therefore benefit from additional restaurant vouchers.

# INTERNAL REGULATIONS

## ❖ ARTICLE 3- SALARY AND BENEFITS

### Article 3-1 Salary°

Salaries shall be paid at the latest on the last day of the month.

### Article 3-2 Mutual insurance°

The general Social Security regime shall guarantee social insurance coverage for all employees.

EURORDIS offers a supplementary mutual insurance package for healthcare and providence guaranteeing an increased level of coverage in the instance of incapacity to work, invalidity or death.

The association has subscribed a compulsory collective agreement for groups of executives and an optional agreement for non-executives.

### Article 3-3 Transport allowance

EURORDIS shall reimburse one half of season tickets (L of 17/12/2008 and of 1/01/09) (multiple season tickets, monthly or weekly passes, bicycle hire scheme registration) for public transport or shall pay a percentage of expenses for the use of a personal vehicle by an employee.

Upon the initiative of the employer, justifications of these expenses may be requested during the year.

Volunteers shall be entitled to receive full reimbursement for all transport costs upon presentation of justification and within the limitations prescribed by law.

### Article 3-4 Restaurant vouchers

Each employee shall be entitled to the allocation of a voucher (Article R 3262-7 of the French Employment Code) per day of work undertaken, with the employer paying for 50% of the total face value of the voucher.

Volunteers shall be entitled to be reimbursed in full for their meal expenses upon presentation of justification and within the limitations prescribed by law.

### Article 3-5 Gift vouchers°

Gift vouchers may be received within the limits prescribed by the French Employment Code.

### Article 3-6 Entitlement to training°

EURORDIS ensures that personnel are adapted to their roles and oversees the continuation in their capacity to occupy employment in view of developments in the role, in technology and in the organisation.

Training activities may be recommended by the employer. These may include proposals made by the staff delegate in addition to individual requests made by employees.

An individual entitlement to training (DIF) may be requested by the personnel. This entitlement allows employees with a certain threshold of service (fixed-term contracts of 4 months or open-ended contracts of one year) to take advantage of vocational training programmes, remunerated or compensated, and which can be followed during or outside of working hours.

Requests for such training should be issued in writing. The choice of training programme to follow must be undertaken by mutual agreement between the employee and the employer.

The objective is to allow for an allocation of time which can be invested in training programmes so as to ensure continuous professional development.

Employees shall be entitled to 20 hours per year which can be accumulated over 6 years and capped at 120 hours.

Employees shall be informed annually of their entitlement.

Hours spent on training during working hours shall constitute actual time worked and shall therefore mean that employees are entitled to receive remuneration.



## INTERNAL REGULATIONS

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Any training programme undertaken outside of working hours shall mean that employees are entitled to receive a special allocation. Aside for in the case of dismissal for gross misconduct, unused individual entitlement to training (DIF) hours may be carried over.

Individual training leave (CIF) represents a more complete training curriculum lasting for one year as a placement or for 1200 hours in continuous education.

This request must be issued in writing.

The notice period is 60 days for placements of less than 6 months or 120 days for placements in excess of 6 months.

The objective of this mechanism is to enable employees to follow training programmes so as to acquire a qualification, to improve skills or to change professional area.

In the event of acceptance of the planned training, 60 to 90% of the salary level can be maintained.

### Article 3-7 Well-being, welcome and friendliness

In a spirit of well-being at work, of welcome and friendliness for employees, volunteers, trainees, temporary staff and guests:

- A pleasant, well-designed, well-decorated and clean environment is made available to all following the wishes of the management of the association and thanks to the support it receives, notably from donations received by AFM-Téléthon fund-raising. Each individual has the responsibility of participating in maintaining this environment and aiming to improve this for general well-being.
- Mineral water, coffee, a selection of teas, sweet and savoury snacks, dishes and napkins are provided free of charge in reception and meeting rooms. Each individual should ensure that the premises are kept clean and tidy, and to always remember the cost such services represent so as to avoid any waste, and to contribute occasionally by offering one's own contributions to the association.



## ARTICLE 4- EMPLOYEE RIGHT OF EXPRESSION

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EURORDIS has a representative body for personnel in addition to suitable communication means to ensure that employees have an adequate right of expression.

### Article 4-1 The role of staff delegates (COMPULSORY)

The staff delegate and their replacement are elected every 4 years.

The mission of the latter is to table individual and collective requests, to oversee application of the French Employment Code, laws regarding social protection, health and safety, and also to inform the employer in the case of any breach of entitlements, of health and safety and individual freedoms.

Meetings with the staff delegate shall take place once monthly, Questions from staff and volunteers present shall be issued to the employer two days prior to the meeting. Duly motivated questions and answers shall be issued electronically in writing, and a paper version shall be left for free access in the staff delegate register within six working days following the date of the meeting.

### Article 4-2 Direct and collective right of expression

EURORDIS shall organise weekly meetings which shall involve all or part of the workforce. The objective of such meetings shall be to allow all issues regarding management and work coordination to be discussed, and to allow people from throughout the organisation ladder to express opinions.

This essential right of expression for EURORDIS will enable communication between all individuals to be improved as well as working conditions and business organisation.

# INTERNAL REGULATIONS

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## ❖ ARTICLE 5 PENALTIES AND RIGHT OF DEFENCE (COMPULSORY)

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### Article 5-1 Scope°

Any case of misconduct as observed by the employer may be subject to the hereinafter listed penalties in accordance with its nature and seriousness.

### Article 5-2 Scale of penalties°

- Blame: written reprimand for conduct at fault
- Warning: written observation intended to raise awareness
- Disciplinary suspension: maximum of five days: unpaid temporary suspension of employment contract
- Transfer: transfer to an alternative post of equivalent level
- Downgrading: transfer to an alternative post of lower level with a drop in remuneration
- Definitive dismissal for disciplinary fault: with or without notice, with or without severance pay and with or without compensation for annual paid leave in accordance with the seriousness of the misconduct

### Article 5-3 Disciplinary procedure°

Pursuant to article 122-41 of the French Employment Code, no penalty whatsoever may be taken against an employee without first inviting said employee to a meeting which indicates the grievances against the latter and the planned penalties.

Said employee shall be entitled to receive assistance during this meeting.

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## ❖ ARTICLE 6 HEALTH AND SAFETY (COMPULSORY)

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### Article 6-1 Health and safety

Each member of staff must have familiarised themselves with the legal and regulatory provisions pertaining to health and safety as appearing in this article and in all displayed service notes.

Personnel have individual drawers which may be locked. These must be kept clean at all times and emptied at least once per year, for the purposes of cleaning.

The supply of water, coffee, tea and other snacks is provided by EURORDIS.

It is hereby understood that each individual shall be responsible for ensuring that the workplace is kept clean and tidy and shall ensure that all mess is tidied after eating.

Any refusal by an employee to respect health and safety requirements may lead to one of the penalties for which provision is duly made in these regulations. Employees shall additionally ensure that they adopt a correct attitude, and respect those around them in addition to respecting all regulations in force.

### Article 6-2 Prevention and safety

Each member of staff must have familiarised themselves with safety instructions which are displayed on site and be aware of the seriousness of possible consequences for failure to respect said instructions.

It is hereby prohibited to handle safety apparatus (extinguishers, stretchers, etc.) for any non-standard usage or to hinder access thereto.



# INTERNAL REGULATIONS

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It is hereby prohibited to render any safety device out of action.

For reasons of safety (e.g. in the event of fire), no internal doors must remain locked following exit of the workplace.

Any incident, no matter how minor, arising during work (or en route to work) must be informed to the line manager of the person concerned as soon as practically possible on the same day of said incident, or, at the latest, within 24 hours thereafter, aside for in any instance of force majeure.

Pursuant to the aforementioned instructions, each employee must oversee, in accordance with training received and the possibilities, their own health and safety and that of their colleagues.

Pursuant to legal provisions in force, personnel shall be bound to undergo compulsory periodical medical checkups in addition to medical checkups at the time of recruitment and recommencement of employment.

Refusal by an employee to respect the health and safety provisions and medical checkups may lead to the application of penalties as indicated in these regulations.

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## ❖ ARTICLE 7 ENTRY INTO FORCE AND AMENDMENTS (COMPULSORY)

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### Article 7-1 Effective date

These regulations, which have been displayed in accordance with the provisions of the French Employment Code and recorded with the secretariat of the industrial tribunal, shall enter into force on .

These internal regulations have been subject to negotiations by all personnel in order to collect opinions prior to publishing the definitive version thereof. Pursuant to article L. 1321-4 of the French Employment Code, the definitive version has been submitted to members of the Staff Delegation Committee in addition to the workplace inspectorate.

### Article 7-2 Subsequent amendments

Any subsequent amendment whatsoever or any withdrawal of any clause appearing in these regulations shall be subject to the same procedure, it being understood that any clause appearing herein that breaches any legal or regulatory provisions applicable to the association due to amendments in these provisions, shall be deemed null and void by right.

Published in Paris, on [date]  
The Director or their representative

Signature



## CHARTER OF THE EURORDIS VOLUNTEERS

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The EURORDIS volunteers are engaged in various activities to achieve the same objective, i.e. help EURORDIS fulfil its mission to build a strong pan-European community of rare disease patients and fight against the impact of rare diseases on peoples' lives.

Volunteers contribute their time, experience and commitment to EURORDIS to carry out different tasks, using their knowledge and best skills.

Volunteers can:

- Represent EURORDIS in international/ European and/or national committees
- Represent EURORDIS in international/European and/or national conferences
- Participate in internal task forces, working groups, committees, advisory groups or panels of experts
- Be involved in project steering committees, in conferences' programmes and/or organising committees
- Take an active part in activities such as moderating online rare disease patient communities
- Provide translations of documents and other activities

EURORDIS recognises and appreciates the work and dedication of its volunteers. The diversity of their competences, rare diseases and countries of origin all play a very important role and constitute a strength of the organisation.

EURORDIS volunteers are not paid or financially compensated for their contribution. They are reimbursed for expenses directly incurred in the scope of their activity in a fair and timely manner according to the internal rules & procedures (a copy of which is issued to all parties), and covered by EURORDIS' insurance when travelling for their mission.

EURORDIS volunteers are committed to:

- Adhering to the core values as adopted by the members of EURORDIS:
  - Mutual respect
  - Solidarity and mutual support
  - Equity and social justice
- Respecting the Terms of Reference of their particular mission; each EURORDIS activity involving volunteers has Terms of Reference adopted by EURORDIS governance and accepted by each volunteer
- Fulfilling their mission based on the core competences upon which they have been nominated:
  - Voluntarism
  - Professionalism
  - Capacity to ensure regular communication with different relevant stakeholders and listen to opinions and requests
  - Capacity to report regularly on their activities
  - Belief in progress
- Reporting to their contact staff person on policy issues and/or delicate matters that require an official position of EURORDIS in line with the organisation's governance practices
- Contributing to developing and raising awareness of EURORDIS and the rare disease patients community in accordance with EURORDIS policy and objectives

EURORDIS is committed to:

- Ensuring that the vision, mission and core values of the organisation are respected
- Providing the volunteers with the necessary tools and staff support to fulfil their mission
- Providing the volunteers with the necessary training and guidance to empower them to carry out their tasks
- Ensuring regular communication with the volunteers, and listening to their opinions and requests
- Valuing, politically and economically, the contribution of volunteers in the fulfilment of their mission

EURORDIS volunteers work closely with the staff as well with each other, providing support and team spirit. This mutually supportive team spirit includes the Board of Directors. Their common aim is to break the isolation of rare disease patients and their families.

Volunteers raise awareness of rare disease patients' needs amongst the general public and policy-makers and advocate for timely access to diagnosis, adequate care, treatment and adapted services.

[Type text]



## Membership Criteria

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The current EURORDIS membership criteria were adopted by the EURORDIS Board in 2007, and have been regularly revised since then with the most recent revision having taken place in November 2015, taking on board comments made at the General Assembly 2015 Madrid.

### Criteria for full membership are as follows:

#### Patient organisations:

- That are rare disease organisations according to EU prevalence criteria (5/10 000) as defined in the: EU Regulation on Orphan Medicinal Products (1999), Commission Communication on Rare Diseases (2008), Council Recommendation on an Action on Rare Diseases (2009), and Directive on Patients' Rights in Cross-Border HealthCare (2011)
- From a European country (48 countries as defined by EURORDIS based on definitions by the EU, the Council of Europe and the WHO-Europe)
- With governing boards made up of a majority of rare disease patients or of family members of patients
- That are financially independent, particularly from the pharmaceutical industry (max. 50% of funding from several companies)
- Holding non-profit status
- With proven activities such as patient support and/or advocacy activities and/or research
- Patient organisation that have been recently (less than 1 year) created are invited to apply for "full membership", but will qualify for a provisional status as "associate member" After one year or more, their membership status can be revised by the board of directors, upon examination of their first annual report or other documents provided to show activities & proof of compliance with the membership rules

*One, or all, of these criteria could be waived in exceptional cases, due to the particularity of patient-driven organisations and of rare diseases, as well as for historical or contextual reasons; in exceptional circumstances, the funding criteria can be waived based on the Board's individual assessment of the independence and structure of funding in addition to the track record of activity and the reputation of the applicant patient organisation. In all cases, the Board of Directors makes the final decision regarding membership, and is not obliged to disclose the reasons of this internal decision, which are recorded in the minutes.*

### Associate membership

Rare disease organisations from countries outside of Europe or those exclusively dedicated to diseases with a higher prevalence than 5/10 000 can become **associate members**.

[Type text]



## Reassessment process

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**A self-reported update form and request for an annual report & composition of the Organisation's Board of Directors is sent to the following organisations every year:**

1. Member organisations that present a candidate to the EURORDIS Board elections
2. National Alliances & European Federations
3. Full members that joined EURORDIS 10 years before the year of the last update



# BECOMING a MEMBER



## OF EUORDIS

THE EUROPEAN ORGANISATION  
FOR RARE DISEASES

[eurordis.org](http://eurordis.org)



**EUORDIS**  
Rare Diseases Europe





**EURORDIS** is the voice of rare disease patients in Europe. We federate over **600 PATIENT ORGANISATIONS** representing over **4000 RARE DISEASES** in **60 COUNTRIES**.

We are the voice of **30 MILLION PEOPLE** living with rare diseases in Europe.

Our strength is in numbers and in coordinating our actions. Together we represent a broad range of diseases and countries. This gives legitimacy to the network and increases our impact.

“

EURORDIS is an outstanding and excellent example of a dynamic, collaborative organisation that helps people in all the European Union States to work together for the Rare Disease community.

*Richard West (Behçets Syndrome Society, United Kingdom)*

”



**EURORDIS**  
Rare Diseases Europe





# WHAT DOES EURORDIS DO FOR THE RARE DISEASE COMMUNITY?



## Advocating for you and with you

**EURORDIS** represents patients within European government institutions and advocates for policies which address the needs of patients and their families. We consult our membership and other stakeholders extensively in developing each advocacy action.

## Building your community

**EURORDIS** brings the rare disease community together. We enable patients to share information and learn from each other. We facilitate platforms like the Council of National Alliances and the Network of European Federations, and services like RareConnect Online Patient Communities where the rare disease community can grow and thrive.

## Shaping policies that take your needs into account

**EURORDIS** conducts surveys and manages projects that aim at giving patients a voice in the health care policy that affects them. Based on these, we propose policy measures and social services adapted to the situation and special needs of people living with rare diseases. We promote the sharing of good practices amongst our members.

## Informing & Raising Awareness

Positive change for people living with rare diseases cannot happen if decision-makers, health professionals, researchers and the general public are not aware of rare diseases and what they mean.

**EURORDIS** uses its pivotal position in the rare disease community to inform, educate and raise awareness about rare diseases.

## Working in partnership to advance Research

**EURORDIS** contributes to the promotion and maintenance of rare diseases as a priority in EU research policy and funding schemes. We defend the interest of patients in European research networks and empower patients in clinical research activities.

## Promoting Drug Development & Access to Treatments

**EURORDIS** intervenes in the orphan drug, advanced therapies and paediatric-use regulatory process and works with industry to speed up the development and ensure the same availability of treatments in all EU countries.

## Training patient advocates

Research advances in the field of rare diseases could not be possible without patient participation in clinical trials, registries and biobanks. **EURORDIS** provides training programmes and resources to strengthen the capacity of patients' representatives to advocate effectively in all aspects of therapy development.



# WHY BECOME A MEMBER OF EURORDIS?

JOIN A VIBRANT PAN-EUROPEAN COMMUNITY OF DEDICATED PEOPLE FACING SIMILAR ISSUES AND STRENGTHEN THE VOICE OF PEOPLE LIVING WITH RARE DISEASES IN EUROPE AND BEYOND.

.....

## Membership Benefits

- ▶ Join a community of more than 600 patient organisations across the world
- ▶ Be represented at key European Institutions, such as the European Commission, the European Medicines Agency (EMA) and at all stakeholder forums
- ▶ Participate in the **EURORDIS** Membership Meeting, conference and capacity building workshops
- ▶ Be listed on the **EURORDIS** website with a direct link to your website
- ▶ Preferential registration rates to the European Conference on Rare Diseases & Orphan Products (ECRD)
- ▶ Post your news and announcements on the **EURORDIS** website
- ▶ Participate in training sessions, such as the **EURORDIS** Summer School for Patient Advocates in Drug Development, Clinical Trials & Regulatory Affairs
- ▶ Privileged access to fellowships to attend conferences such as the European Conference on Rare Diseases & Orphan Products (ECRD)
- ▶ Set up an online patient community for your disease through [rareconnect.org](http://rareconnect.org)
- ▶ Be a privileged Rare Disease Day participant (last day of February each year, [rarediseaseday.org](http://rarediseaseday.org))
- ▶ Vote at the General Assembly (Full members only)
- ▶ Be elected to the Board of Directors of **EURORDIS** (Full members only)

“

EURORDIS is the most important organisation representing people with rare conditions in Europe. It has excellent contacts within the European Union, where it is a respected advocate and has patient representatives on the key committees relevant to rare disease therapy development at the European Medicines Agency... It is also extremely helpful as a source of information and networking. Those of us who are already members know just how valuable EURORDIS is, both in helping to set the international agenda and as an important source of information and support nationally.

*John Dart (Debra International)*

”

“

From the start of our patient organisation, EURORDIS has provided us with a very professional structure of support. EURORDIS colleagues were of invaluable help in our advocacy battle for new medicines for the multiple myeloma patients.  
*Greetje Goosens (EMP, European Myeloma Platform)*

”

## WHAT IS REQUIRED OF YOUR ORGANISATION?

- ▶ Nominate a contact person (English speaking if possible) who will be the primary link with **EURORDIS**
- ▶ Pay the annual membership fee (see page 7 for details)
- ▶ Keep us informed of changes in your organisation (Board of Directors, contacts, funding, financial data, etc) and send your annual reports

“

Thank you for the opportunity to be involved, make friends, be treated like normal and especially for the fact that you help us go beyond the pain of our conditions and bring out the best in us, transforming a tragedy into a cause...

*Camelia Lazar (Williams Association, Romania)*

”

## HOW CAN YOU PARTICIPATE?

- ▶ Attend the **EURORDIS** Membership Meeting and European Conference on Rare Diseases & Orphan Products (ECRD)
- ▶ Take part in some of our projects
- ▶ Participate in regular surveys
- ▶ Contribute to **EURORDIS**' strategic orientations through its position papers, Committees and Policy Task Forces
- ▶ Put forward candidates (patients or medical experts on your disease) for European Medicines Agency committees or meetings
- ▶ Be a candidate for the **EURORDIS** Board of Directors (Full members only)
- ▶ Vote at the General Assembly (Full members only)



## WHO CAN APPLY?

### Patient organisations:

- ▶ That are rare disease organisations according to EU prevalence criteria (5/10 000) as defined in the: EU Regulation on Orphan Medicinal Products (1999), Commission Communication on Rare Diseases (2008), Council Recommendation on an Action on Rare Diseases (2009), and Directive on Patients' Rights in Cross-Border HealthCare (2011)
- ▶ From a European country (48 countries as defined by EURORDIS based on definitions by the EU, the Council of Europe and the WHO-Europe)
- ▶ With governing boards made up of a majority of rare disease patients or of family members of patients
- ▶ That are financially independent, particularly from the pharmaceutical industry (max. 50% of funding from several companies)
- ▶ Holding non-profit status
- ▶ With proven activities such as patient support and/or advocacy activities and/or research

Patient organisations that have been created recently (less than 1 year ago) are invited to apply for full membership, but will qualify for a provisional status as **“associate member”**. After one year, and upon examination of their first annual report or other documents provided to show activities and proof of compliance with the membership rules, their membership status can be revised by the Board of Directors.

**One or all of these criteria can be waived in exceptional cases, due to the particularity of patient-driven organisations and of rare diseases, as well as for historical or contextual reasons. In all cases, the Board of Directors makes the final decision regarding membership and is not obliged to disclose the reasons of this internal decision, which are recorded in the minutes of the Board meeting.**

Rare disease organisations from countries outside of Europe or those exclusively dedicated to diseases with a higher prevalence than 5/10 000 can become **associate members**.

### Annual review process for regular re-assessment of FULL Members

**A self-reported update form and request for an annual report & composition of the Organisation's Board of Directors is sent to the following organisations every year:**

1. Member organisations that present a candidate to the EURORDIS Board elections
2. National Alliances & European Federations
3. Full members that joined EURORDIS 10 years before the year of the last update  
(all full members that joined before December 2013 were sent the reassessment form in 2014)

## HOW DO YOU APPLY?

**To apply for membership, simply complete and return the membership application form with the following documents:**

- ▶ Statutes of your organisation
- ▶ The names of your Board of Directors, indicating for each person whether they are patients or family members of patients
- ▶ Your most recent Annual Report (including the financial statement)
- ▶ A short description of your main activities and goals (in English if possible)
- ▶ Publications and/or educational materials (if available)



## WHO IS YOUR CONTACT?

- Anja Helm, Senior Manager, Relations with Patient Organisations  
**EURORDIS**  
 96 rue Didot 75014 Paris FRANCE  
 Tél: +33 (0)1 56 53 52 17 Fax : +33 (0)1 56 53 52 15  
 Email: [anja.helm@eurordis.org](mailto:anja.helm@eurordis.org)

## HOW DO YOU KNOW IF YOU HAVE BEEN APPROVED?

Once we have received all the relevant information, your application will be examined by our staff and submitted at the next Board of Directors or Board of Officers meeting.

- If the application is approved by the Board of Directors, your organisation receives a welcome e-mail and the EURORDIS member logo. The applicant organisation is officially a member of **EURORDIS** once the first annual membership fees have been received.
- If the application is rejected by the Board of Directors, the organisation receives a notification letter from the President.

## MEMBERSHIP FEES

Full membership fees are based on your organisation's annual budget (previous year):

Annual budget	Full membership fee
Less than 10,000 euros	25 euros
Between 10,000 and 99,000 euros	75 euros
Between 100,000 and 499,000 euros	200 euros
Between 500,000 and 999,000 euros	600 euros
Over 1,000,000 euros	1,250 euros

Associate membership fees are independent of your organisation's budget.

### Associate membership fee

25 euros

Membership fees are annual and renewed every January.  
 The amounts of the fees are decided by the General Assembly.

## JOIN US NOW!



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## **EURORDIS Board Members Role and Responsibilities**

### *Rules & Commitment*

- The Directors are elected by the Annual General Assembly among individuals nominated by the full members of the Association, for a period of three years. The Board is renewed annually by election of the Directors to fill the seats falling vacant, outgoing Directors are eligible for re-election.
- It is desirable for the Board to include Directors from as wide a scope as possible both in terms of pathology and geography to ensure that EURORDIS is truly representative.
- Each board member represents the interest of rare disease patients from all European countries; they do not represent the interest of their own country or disease.
- Each full member of EURORDIS can nominate a candidate to serve on the Board, this nomination must be made by the legal representative of the candidate organisation, and the organisation must be up-to-date with their membership fees.
- It is the individual representative, which is elected on the Board of EURORDIS, not the member organisation.
- The Board of Directors meets at least once every six months, meetings are usually organised three times per year, usually in Paris, although they may exceptionally be organised in a different city, plus one Board meeting at the Annual General Assembly.
- Directors do not have an alternate and should accept that unjustified absence from two consecutive Board of Directors meetings could result in dismissal.
- Directors should accept that membership of the Board is of an enduring nature and that a minimum of three months' notice of resignation is required.
- Directors act in the scope of and in accordance with EURORDIS' Statutes and By-Laws and report to the General Assembly.

### *Role*

- To direct EURORDIS towards the realisation of its mission.
- To ensure that EURORDIS has a long-term strategy to achieve its objectives and towards which it makes consistent progress.
- To ensure the good governance of EURORDIS.
- To ensure that EURORDIS and its assets are effectively managed. The Board of Directors decides on all questions relating to acquisitions, exchanges, disposal or rent, mortgages and loans for the pursuit of the Association's objectives.

## Responsibilities

### **Planning**

- Participate in creating and reviewing strategic orientations.
- Approve, on an annual basis, the action plan, budget, projects.
- Act as a collegiate body with collective responsibility.

### **Organising**

The Board of Directors:

- Appoint, support and monitor the Chief Executive Officer.
- Review Board performance and take regular steps to develop and improve this performance.
- Draft, adopt, monitor and update the EURORDIS' by-laws which determine the application details of the Statutes
- Select Officers from its members, by secret ballots, composed of a President, a Vice-President, a Secretary, a Treasurer, and if necessary up to two additional officers. All Officers are elected for a period of one year and eligible for re-election at the end of their terms. The Board of Directors oversees the activities of the Board of Officers which report to it.
- Ensure the organisational basis (personnel and financial) of Eurordis is adequate to meet its operational needs.

### **Operations**

- Attend Board meetings, having read e-mails and papers in advance of meetings.
- Participate in and support appropriate committees within the Board or externally to represent the policies and concerns of EURORDIS.
- To write a short report of all meetings, conferences etc. attended on behalf of EURORDIS, and forward to EURORDIS all presentations made at these events (the so called EPAC reports, short for European Public Affairs Committee Report)
- To contribute specific skills, interests and contacts to the development of EURORDIS and its aims.
- To appoint EURORDIS representatives when necessary.

### **Membership**

- To strengthen the membership base in your country, by encouraging membership applications.
- To examine membership applications from candidates from your country or your disease.
- To ensure that the member organisations from your country pay their fees.
- To be responsible for the admission or the expulsion of members according to EURORDIS statutes.

## Person Specification

### **Essential**

- Fluent English, both spoken and written.
- Ability to commit time to meetings and preparation of meetings (at least twelve whole days equivalent per year).
- Ability to act as EURORDIS representative, to inform of its activities and encourage new membership.
- Ability to work as part of a multi-cultural team.

### **Desirable (any of the skills below are valuable)**

- Personal knowledge/association with a rare disease.

- Knowledge of medical, social or regulatory issues around chronic illness, disability or rare disease.
- Experience of working as a patient advocate and/or within multi-stakeholder committees. Ability/confidence to work effectively at conferences and workshops as speaker or participant.
- Experience of working with the European Commission.
- Experience of project work.
- Ability to participate effectively in teleconferences or similar when face-to-face meetings cannot be scheduled.





## **EURORDIS General Secretary Role and responsibilities**

### **Main Responsibilities**

- Ensure that EURORDIS operates within the legal framework set out in French law for a not-for-profit association “Loi 1901” with the support of the Chief Executive Officer and the Senior Staff and, if necessary, external legal advice.
- Ensure that EURORDIS operates within the terms of its statutes and by-laws, and that this is communicated throughout EURORDIS and to its members.
- With the support of the Board members, of the Chief Executive Officer and of the manager of relations with patient organisations, promote and monitor membership.
- Represent and speak on behalf of EURORDIS in external relations where most relevant.

### **Management of the Organisation**

- Assist the President in the implementation of the decisions of the Board of Directors by reviewing progress from the Tracking Table of Actions and Decisions.
- Together with the President, and the Chief Executive Officer, ensure that EURORDIS develops and applies good practice in the organisation’s governance and transparency.
- Together with the Chief Executive Officer, and the Communications staff, ensure that the activity report is a true record of the services of EURORDIS.

### **Organisational Responsibilities**

- Ensure that Minutes of the Board of Directors and the General Assembly meetings and that the Table of Actions and Decisions of the Board of Officers are written, that these are a true record, and that they are signed and registered in due time.
- Assist in deciding the date, place and agenda of the General Assembly.
- Ensure that changes in the Board of Directors and relevant documents are communicated to the relevant authorities.

### **Commitments**

- The General Secretary is asked to give at least 3 months’ notice of resignation, whether or not this includes resignation from the Board.

## **EURORDIS President Role and Responsibilities**

**In the President's absence this would be the Vice-President's role**

### **Main Responsibilities**

- 1 To promote the future direction of EURORDIS.
- 2 To ensure that the Board of Directors fulfils its governance responsibilities
- 3 To ensure EURORDIS is achieving the objectives set, through the Chief Executive Officer, in partnership with the Senior Staff.
- 4 To represent and speak on behalf of EURORDIS in external relations where most relevant.

### **Main duties relating to:**

#### **1 Promoting the direction of Eurordis:**

- Set targets, together with the Board and facilitate proposals for the future direction of EURORDIS.
- Assess the right direction of the organisation, according to its vision and mission
- Ensure that the Directors set overall strategy, i.e. orientations and annual action plan, with objectives which can be monitored.
- Serve as an additional spokesperson for or promoter of EURORDIS to a wider audience of potential donors and beneficiaries.

#### **2 Fulfilment of governance responsibilities:**

- Approve the draft agenda, of both Board of Directors and of Officers meetings, as well as Assemblies.
- Chair meetings both of the Board of Directors and of Officers, as well as Assemblies; ensure that they function effectively and carry out their duties.
- Listen to every Board member opinion and be as impartial as possible when closing every topic, ensuring that the conclusion /decision of every topic in the agenda is balanced and takes into consideration everyone's opinion
- Maintain a good atmosphere in Board meetings and good mutual support and respect among Board members.
- Ensure that the business of meetings (Board and Assemblies) is dealt with and that decisions, when required, are clearly established and recorded, and their implementation monitored.
- Ensure that EURORDIS' financial dealings are prudently and systematically accounted for, audited and publicly available.
- Ensure, together with the Finance Director and the Treasurer, that financial and activity reports are a true record of the services and financial position of EURORDIS.
- Ensure that the Board reviews its structure, role and relationship to staff and implements agreed changes as necessary.
- Appoint EURORDIS representatives in consultation with the Board.
- Delegate some of his/her responsibilities to other Directors.

**3 To ensure EURORDIS is achieving the objectives set, through the Chief Executive Officer, in partnership with the Senior Staff:**

- Monitor progress in implementing the annual Work Programme.
- Ensure that available resources (personnel, financial, material) are appropriate to the goals.
- Ensure that appropriate arrangements are in place to support, monitor and review the work of the Chief Executive Officer.
- Through the Chief Executive Officer, ensure appropriate communication between the Board of Directors and the staff or volunteers.
- Ensure that EURORDIS has appropriate procedures to:
  - comply with employment legislation and good practice;
  - develop and update job descriptions;
  - issue and abide by contracts of employment;
  - ensure appropriate induction, training, supervision and review of staff;
- Set, with the Board, an annual calendar of Board meetings and major EURORDIS events.

**4 Represent and speak on behalf of Eurordis**

- Serve as an additional spokesperson for, or promoter of, EURORDIS.
- Be assisted by the staff when preparing representation of EURORDIS in meetings and conferences
- Help promote EURORDIS to a wider audience of potential donors and beneficiaries.

**Commitment**

The President and Vice-President are asked to give at least 3 months' notice of resignation, whether or not this includes resignation from the Board.



## **EURORDIS Treasurer Role and Responsibilities**

### **Main Responsibilities**

- Maintain an overview of EURORDIS, ensuring that it operates within the legal and financial guidelines set out in current legislation.
- Ensure that EURORDIS operates within the terms of its statutes and by-laws and that this is communicated throughout EURORDIS and to members.
- Provide periodical treasurer reports to EURORDIS Boards.

### **Management of the Organisation**

- With the President, the Chief Executive Officer and Senior Staff, ensure that EURORDIS has a long-term financial strategy to achieve its objectives and towards which it makes consistent progress.
- Ensure that appropriate resources (financial and material) are secured and maintained a standard relevant to EURORDIS' objectives.
- Ensure other directors, and mainly the President, that EURORDIS' developments are secure enough, that growing of budget is managed with an acceptable risk.

### **Human Resources**

- Ensure that the staff has the proper skills and means to manage Human Resources properly.
- Validates the CEO's Reimbursement claim forms

### **Financial Responsibilities**

- Ensure that EURORDIS' financial obligations are met and all financial dealings are accounted for in respect of:
  - wages and any other pay or benefits due to employees under legislation or the terms of their contracts with EURORDIS
  - mortgages, rent, rates and insurances
  - all other bills
- Ensure that all grants or other funds received for specific purposes are spent as specified.
- Ensure that EURORDIS keeps accurate and comprehensible accounts, accessible to the Board and authorised members of staff.
- Ensure the timely preparation of the annual budget and its submission to the Board in accordance with approved procedures.
- Ensure that annual accounts and audits are prepared and carried out.
- Ensure with the Chief Executive Officer, the Financial Director and auditors, that financial reports are a true record of the financial position of EURORDIS.
- Seek to identify any financial risks facing EURORDIS and recommend

- appropriate action.
- Liaise with, and recommend appointment of auditors to the Board.

### **Commitment**

The Treasurer is asked to give at least 3 months' notice of resignation, whether or not this includes resignation from the Board.

## Internal Rules

### The Network and Council of National Alliances (CNA)

*Since its creation, EURORDIS has encouraged and supported the creation of National Alliances for Rare Diseases progressively in all EU member states and beyond. Currently, there are 39 National Alliances who are members of EURORDIS, of which 36 form the European Network of National Alliances for Rare Diseases. The latter are all organisations recognised as “National Alliances of Rare Disease Patient Organisations” by the EURORDIS Board of Directors. The European Network of National Alliances for Rare Diseases is governed by the Council of National Alliances.*

*The European Network of National Alliances for Rare Diseases aims to foster the visibility and recognition of National Alliances, to take the patient voice to a higher and stronger level, to enhance EURORDIS’ outreach to local patient groups to build a pan-European community of people living with rare diseases, to strengthen rare disease patient group capacities as well as to empower patient advocates.*

*As part of its mission to build a strong pan-European community of patient organisations and to develop a broader grassroots patient-centred community, EURORDIS has set up the goal (as detailed in the EURORDIS Strategies 2010-2015 and 2015-2020) to develop more supportive capacity building relationships with its members, including intensifying capacity-building and networking with and between the National Rare Disease Alliances to improve efficacy.*

*To this end, EURORDIS and the National Alliances have developed a shared process that aims to promote greater convergence and collaboration between National Alliances themselves, and between National Alliances and EURORDIS, through their Strategies and Annual Work Plans, as well as their Strategic Partnerships for an optimal synergy. This shared process is referred to “Common Goals & Mutual Commitments between National Alliances in Europe and EURORDIS: An agenda between 2014 & 2020”.*

### **Eligibility criteria for a National Alliance to be recognised by EURORDIS:**

To be recognised as a National Alliance in Europe an organisation must:

1. Firstly, be a full member of EURORDIS:
  - Rare disease organisation according to EU prevalence criteria (5 / 10 000);
  - Organisation from a European country;
  - The Governing Boards should be made up of a majority of rare disease patients, parents or close relatives of patients;
  - Financial independence, particularly from the pharmaceutical industry (max. 50% of funding, from several companies.);
  - Non-profit status;
  - Proven patient support and/or advocacy and/or research activities

2. Secondly, comply with the four following criteria:

- Represent rare disease organisations from a wide range of diseases in at least three groups of diseases (such as immunology, oncology, cardiovascular, infectious, metabolic, neuromuscular, etc.),
- Federate patient organisations from their European country,
- Have a significant number of members, compared to the number of patient groups existing in their country, with clear membership rules,
- Agree to and sign the “Common Goals & Mutual Commitments between National Alliances in Europe and EURORDIS: An agenda between 2014-2020”.

A National Alliance in Europe recognised by EURORDIS automatically becomes a member of the European Network of National Alliances for Rare Diseases and a member of the Council of National Alliances.

EURORDIS may develop a relation with National Alliances not fulfilling all criteria, in which case they are recognised as Associate Members to the CNA. This applies in particular to National Alliances newly established in Europe and to Regional Alliances.

National Alliances based outside Europe can apply to join the CNA as observers.

While the National Alliances encourage their members to become full members of EURORDIS, some patient groups may choose not to apply for membership and consider themselves represented indirectly through their Alliance.

### **General Objectives of the Council of National Alliances (CNA):**

The Council of National Alliances is defined in the Statutes of EURORDIS, article 10-1, as adopted at the Annual General Assembly, May 2016 in Edinburgh, United Kingdom.

The major tasks of the Council, as expressed in the EURORDIS by-laws, are:

- i) to strengthen the European Network of National Alliances,
- ii) to participate in relevant EURORDIS activities,
- iii) to provide advice and expertise to the Board of Directors.

Each National Alliance regularly provides information about their governance, membership, strategies & work plans, budget & financial resources, human resources, strengths & weaknesses; key common indicators will be developed; each Alliance will provide EURORDIS with a regularly updated list of their members (including website addresses).

EURORDIS provides information such as the Newsletter or internal memos to National Alliances, which they will do their best to translate and disseminate to their members.

The National Alliances provide information about RD policy from their respective countries. EURORDIS summarises this update in English and disseminates this information among the National Alliances.

In order to promote greater convergence and collaboration between National Alliances and between National Alliances and EURORDIS, the Council of National Alliances and EURORDIS have developed the “Common Goals & Mutual Commitments”, which is signed by all National Alliances. A non-binding Annex provides an Implementation Plan which is governed by the Council of National Alliances.

The Council provides advice to the EURORDIS Board of Directors on various relevant topics at Council or Board initiatives.

## **Organisation**

The Council of National Alliances is made up of representatives from National Rare Disease Alliances.

Each National Alliance appoints a representative and an alternate to the Council. This representative is the contact person for EURORDIS, and must be committed to attending all CNA meetings, and to keeping the alternate up-to-date on all CNA activities in case of the representative’s unavoidable absence.

The Council of National Alliances usually holds two workshops per year. The date of this workshop is announced at the latest three months in advance. The agenda of the workshop is disseminated at least four weeks in advance following a two week consultation period during which the CNA members are invited to propose items for the agenda.

At this workshop the National Alliances exchange their experiences in the approach to different issues concerning rare diseases and collaborates on common goals such as Rare Disease Day and National Plans.

Regular conference calls / webinars are organised on specific topics when needed. The CNA organises working groups where necessary to take charge of specific objectives such as Rare Disease Day, European Year of Rare Diseases, Organising Committee of the European Conference on Rare Diseases.

All CNA decisions are made by consensus, to the extent that this is possible. If consensus is not reached, diverging opinions are accepted and recorded accordingly.



## General financial guidelines

EURORDIS will cover the cost of preparing CNA workshops, meeting rooms and meals.

Each National Alliance will pay for its representative's travel and lodging. Meetings and Workshops can take place in different countries over time. They are usually organised in EURORDIS' Paris Offices and back to back with the annual EURORDIS Membership Meeting which takes place in different locations every year.

National Alliances can apply for the *National Alliances Exchange Program-Learning from Each Other*, which is an exchange Program for National Alliances in the form of Short Term Fellowships to enable more direct exchange, transfer of knowledge and collaboration between one National Alliance with another and to offer means of mutual support and capacity building.

With the support of:



## Common Goals & Mutual Commitments between National Alliances in Europe & EURORDIS: An agenda between 2014 & 2020

EURORDIS & National Alliances aim to the best of their ability and in accordance with available resources to:

- Consolidate their position as the organisations of reference for rare diseases at national level and as European Networks and be recognised as actors in worldwide processes having impacts on patients and families living with a rare disease in Europe;
- Consolidate their activities to raise public awareness, in particular the Rare Disease Day;
- Facilitate the development and the effective implementation of a unique EU integrated, comprehensive and long-term strategy to address patients' needs everywhere in Europe, driven by patient advocacy, developed through partnership of all stakeholders, and guided by regulations & directives (laws), recommendations & communications (policies), road maps & programmes & guiding principles & expert recommendations (technical guidance);
- Facilitate the development and engage in the effective implementation of national plans & strategies for rare diseases;
- Consolidate their joint policy recommendations and activities in drug development, centres of expertise, European reference networks, biobanks & registries, good clinical practices for diagnosis & care, specialised social services & integration of rare diseases within national social policies, patients' advocates empowerment;
- Strive for and maintain supportive capacity building relationships with their members and empowerment of volunteers; have the objective to become sustainable in terms of human, financial, organisational resources and governance.

The Implementation Plan for the fulfilment of these Common Goals & Mutual Commitments is detailed in the Annex. This Annex is non-binding and comprises the Road Map for the National Alliances and the Council of National Alliances. The Annex is open to revisions and adoption by the Council of National Alliances.

The purpose, background rationale & perspective, and process are expanded on in the Letter from EURORDIS addressed to the National Alliances.

The.....(name of Alliance) has decided at its Board of Directors' meeting on..... (date) to progressively integrate to the best of their ability and in accordance with available resources these common goals into its strategy & work plans and to commit to all other National Alliances involved in the European Network of National Alliances for Rare Diseases and to EURORDIS to carry out these common activities to the best of its possibilities.

EURORDIS has decided at its Board of Directors' meeting on 23 November 2013 to integrate to the best of its ability and in accordance with available resources these common goals into its strategy & work plans and to commit to all National Alliances involved in the European Network of National Alliances for Rare Diseases to carry out these common activities.

For the .....(name of NA),

The President

For EURORDIS and on behalf of the European Network of National Alliances for Rare Diseases,



Terkel Andersen  
President



## Implementation Plan of the Common Goals & Mutual Commitments between National Alliances in Europe & EURORDIS

National Alliances & EURORDIS will do their best efforts in order to reach the Common Goals and engage in the Mutual Commitments.

- In order to consolidate their positions as the organisations of reference for rare diseases in Europe and as European Networks and to be recognised as actors in worldwide processes having impacts on patients and families living with a rare disease in Europe, National Alliances & EURORDIS should work together to:
  - Consolidate the **European Network of National Alliances for Rare Diseases**:
    - ❖ Based on the eligibility criteria for National Alliances recognised by EURORDIS,
    - ❖ Based on the Internal Rules of the Council of National Alliances,
    - ❖ Based on a full and regular commitment into the activities of the Council of National Alliances, in sharing information, experience and common activities.
  - Launch “**Rare Diseases International**”:
    - ❖ First as an informal network on a small number of short-term, pragmatic objectives (website, exchange of information & experience, common voice) partnering with the National Alliances in Europe and around the world as well as the international disease specific federations (a starting point 2013),
    - ❖ Then establish it as a formal network so to become the international rare disease patient organisation, and gain visibility and influence in international instances such as WHO, UN and OECD (a Goal by 2020).
  - **Support RareConnect**:
    - ❖ Based on the existing 50 online patient communities (as of 2013),
    - ❖ Engage relevant National Alliances in RareConnect,
    - ❖ Assist in the development of online patient communities for most rare diseases by 2020 in particular the most rare and isolated patients & families, involve carers or clinicians or social workers or researchers, support conversations across communities on common issues in areas of personal life, social life, day to day care, etc. (a Goal by 2020).
  - Consolidate the **common identity** of EURORDIS and National Alliances as being part of the same network:

- ❖ Share a common subtitle name with “**Rare Diseases Europe**” (for EURORDIS) and “**Rare Diseases Country**” (for National Alliances); use a common logo reflecting the network in addition to existing logo; this common identity is implemented progressively (a starting point 2013)
  - ❖ Increase mutual visibility on all communication tools and amplify this common synergetic identity (a Goal by 2020)
- Consolidate the **Membership** of National Alliances in order to cover the majority, and beyond as much as possible, of all existing rare disease patient groups at national level so to enhance their representation and inclusiveness.
- In order to consolidate their activities to raise public awareness, EURORDIS & National Alliances should work together to:
    - **Organise Rare Disease Day** to raise public awareness and empower the voice of the rare disease community through:
      - ❖ The annual International Rare Disease Day (starting point 2013) with bigger campaigns on leap years 2016 and 2020
      - ❖ Coordinated actions to promote Rare Disease Day as an International Day recognised by WHO (a Goal by 2020)
  - In order to facilitate the development and the effective implementation of a unique EU integrated, comprehensive and long-term strategy to address patients’ needs everywhere in Europe, driven by patient advocacy, developed through partnership of all stakeholders, and guided by Regulations & Directives (laws), Recommendations & Communications (policies), Road Maps & Programmes & Guiding Principles & Expert Recommendations (technical guidance), EURORDIS & National Alliances:
    - Consolidate their joint policy actions for the effective implementation of European regulations and strategies at national level in more policy areas to the benefit of patients and families, such as (starting point 2013):
      - ❖ EU Regulation on Orphan Medicinal Products
      - ❖ EU Regulation on Medicinal Products for Paediatric Use
      - ❖ EU Regulation on Advanced Therapy Medicinal Products
      - ❖ EU Regulation on Pharmaceutical Legislation
      - ❖ EU Regulation on Pharmacovigilance Urgent Measures
      - ❖ Commission Communication on Rare Diseases: Europe’s Challenges
      - ❖ Council Recommendation on an Action in the field of Rare Diseases
      - ❖ EU Directive on Cross-Border Healthcare
      - ❖ EU Regulation on Clinical Trials
      - ❖ EU Regulation on Data Protection
      - ❖ EU Regulation on Transparency

❖ Council of Europe Recommendations and Guiding Principles

- Improve **access to orphan medicinal products and other rare disease therapies** for all patients through the gathering of expertise at European level, its recognition at national levels, the interface between regulators/health technology assessors/payers, innovative policies (a Goal by 2020),
  - Advocate for the development of at least **200 new orphan medicinal products and diagnostic tools for most rare diseases by 2020** through the International Rare Disease Research Consortium (IRDiRC), and by the promotion of greater convergence between European & National research strategies & policies and the promotion of patient advocacy driven innovative solutions in partnership with stakeholders (a Goal by 2020)
  - Conduct studies on Access & Delays to Diagnosis, on Experience & Expectations on Care Provision, on Quality of Life, Social Impact & Economic Burden of People Living with Rare Diseases through pan-European cross-diseases **EURORDIS Rare Barometer Surveys and other social research in partnership with academic teams** (a Goal by 2020)
  - Promote an EU legislation to prevent **genetic discrimination** (a Goal by 2020)
  - Develop a synergetic approach towards improving access to validated web-based information resources and relevant customised information, such as EURORDIS Website, , NAs Website, Member Patient Organisations Websites and Help Lines operated by their volunteers, RareConnect, National Help Lines & European Network & Shared Tools & European 116 number, ORPHANET webserver and associated services, through promoting their convergence into one large **European network providing information to patients & families & professionals (a Goal by 2020).**
  - Coordinate EURORDIS' **European Conference on Rare Diseases & Orphan Products** 2014 & 2016 & 2018 & 2020 and NAs' **national or cross-national conferences** in term of planning, programme development, target audiences, official support, mutual promotion (starting point 2013)
- In order to facilitate the development and effective implementation of national plans and strategies for rare diseases, EURORDIS & National Alliances consolidate their joint policy actions to:
    - Promote the adoption of **National Plans/Strategies** in each EU Member State by 2013, renew them based on benchmarking and iterative upgrading (a Goal by 2020) as well as get them adopted or under development in all other European Countries by 2020 with patient-centered approaches around common strategies and technical recommendations, sharing good practices, monitored through common indicators; the main areas are:

❖ Centers of Expertise & European Reference Networks for Rare Diseases

- ❖ Biobanks & Registries & Data Collection
- ❖ Good Clinical Practices for Diagnosis & Care
- ❖ Patients' right to Health Care Cross-Border Mobility
- ❖ Information services through help lines and web-based servers
- ❖ Specialised Social Services and Integration of Rare Diseases within national social policies
- Adjust European & National actions on the basis of feedback from National Alliances on the effective implementation of rare disease regulations and policies (evaluation process by National Alliances) and remaining unmet needs (research budget, centres of expertise, best practice of diagnosis & care, access to diagnosis & care & social services & reimbursement, quality of life) (a Goal by 2020)
- In order to be more sustainable in terms of human, financial, organisational resources and governance, as well develop enriched and more supportive capacity building relationships with members and empowerment of volunteers, National Alliances & EURORDIS should:
  - Regularly **collect, analyse and monitor information** about EURORDIS & National Alliances' governance, membership, strategies & work plans, budgets & financial resources, human resources; develop key common indicators; facilitate exchange of good practices and mutual support (start in 2014)
  - Stimulate and facilitate **information & experience exchange & good practices & common tools to enhance mutual support and learning from each other**, intensify **capacity building and networking** activities of EURORDIS with National Alliances and between National Alliances across Europe both to enhance respective capacities, increase convergence and collaboration between National Alliances across Europe so to strengthen the Alliances and improve overall efficacy (ex: CNA Workshops, EURORDIS Membership Meeting Workshops, EURORDIS Summer School, mailing list, Exchange Programme "Learning From Each Other", joint activities, Policy Fact Sheets, etc) (starting point 2013)
  - Capacity building of EURORDIS volunteer & patient advocates (ex: EURORDIS Membership Meeting Workshops, EURORDIS Summer School, e-learning, webinars)
  - Maintain a high level of **legitimacy and credibility** by maintaining a high level of consent amongst EURORDIS' & National Alliances members as well as a high level of national & European & International public affairs & advocacy alignment amongst EURORDIS & National Alliances & their members (a Goal by 2020)
  - Promote **public recognition and financial support of National Alliances** and EURORDIS based on the recognition of their role as actors in rare disease patient & families' empowerment, information, public health, healthcare and research (a Goal by 2020)

- Exchange information regarding EU funding and projects they could be involved in (starting point 2013)
- Promote private resource development through the joint approach of foundations and corporations (a Goal by 2020)
- Develop joint actions to raise funds. Explore first the co-organisation of events replicable around Europe (a Goal by 2020)





## Internal Rules

### The Network and Council of European Rare Disease Federations (CEF)

*As part of its mission to build a strong pan-European community of patient organisations and to develop a broader grassroots patient-centred community, respectively, EURORDIS has set the goal to better structure its group of European disease-specific networks. The European Network of Rare Disease European Federations is the way to reach that goal.*

*Currently, there are 58 European Federations who are members of EURORDIS, however there are more emerging, rare disease-specific European Federations, amongst which most are already in relation with or involved in EURORDIS' activities.*

*The Network of European Rare Disease Federations aims to complement the Council of National Alliances by increasing EURORDIS' outreach to local patient groups in new and future EU Member states as well as in all regions of Europe. While the Council of National Alliances represents the national level, the Network of European Rare Disease Federations represents the disease-specific level. Both the Council and the Network aim to enhance EURORDIS' outreach to local patient groups to build a pan-European community of people living with rare diseases. In addition, both are instrumental in i) building rare disease patient group capacities, ii) empowering patient advocates and ii) taking the patient voice to a higher and stronger level.*

*The European Network of Federations will specifically enhance EURORDIS' capacity to play an active role in priority policy areas such as European Reference Networks, European research projects, therapy development, web communities and information helplines.*

## General Objectives

The **Network** will enable **European Rare Disease Federations**:

- (a) to share information and experiences relevant to common activities and issues in their specific rare diseases at the European level ,
- (b) to discuss and implement common activities within EURORDIS,
- (c) to foster or build their capacities as European Federations gathering patient groups from different countries for their specific disease or group of diseases,
- (d) to enhance their voice at the European level for their respective diseases,
- (e) to –directly or indirectly- fight against the impact on the lives of people living with the rare diseases these European federations are specifically addressing.

## Specific Objectives:

### 1. To create and develop the Network of European Rare Disease Federations

The Network of European Rare Disease Federations will provide a platform for the exchange of experiences and information across existing European Federations working for different diseases or groups of diseases. The Network will be a link between EURORDIS and the members of the Federations. It will look for synergies and empower their members. The Network will generate more activity at the European level. EURORDIS will invite the European Federations who are not yet members of



EURORDIS to apply for membership and to join the Network of European Rare Disease Federations.

## **2. To participate in the annual international Rare Disease Day**

Each European Federation will be invited to participate in the implementation of Rare Disease Day and to customise the theme and focus to its specific disease.

All members of the Network of European Rare Disease Federations will be invited to join forces with EURORDIS in its activities in Brussels for Rare Disease Day.

## **3. To take part in the project Rare!Together**

The project Rare!Together was launched in 2008 by EURORDIS to support the development of new Rare Disease federations, with the support of Medtronic Foundation and DG SanCo through the Operating Grant OPERA. The project will also develop a “Guide to Establishing and Developing a European Rare Disease Federation” and dedicated website section including a tool kit (developed with a wiki and a blog) useful to all networks and federations.

## **4. To promote and collaborate with European Reference Networks for Rare Diseases (ERN)**

The Network of European Rare Disease Federations will provide a forum to actively collaborate with European Reference Networks for Rare Diseases by:

- Exchanging information and experiences of their collaborations with ERNs
- Initiating and partnering in new applications for ERNs, new full members or new affiliated partners in ERNs
- Developing common tools to enhance the collaboration between ERNs and European RD Federations enlarge to all rare disease patient groups through the EURORDIS' European Patient Advocacy Groups (ePAGs): annual meetings of the ePAGs in conjunction with the EURORDIS Membership Meeting or ERN meetings; capacity building of patient advocates in patient databases and registries, in clinical trials and drug development & EU regulatory affairs, in research activities, in information activities; development of social guidelines; respite care services; therapeutic recreation programmes; etc
- Developing common tools for enhancing communication and the involvement and patients and families as active users of the ERNs and of the CoE: web online patient communities; European helpline; patients & parents leaflets; evaluation by patients; etc
- Using the Declaration<sup>(1)</sup> to promote the need for ERNs for each of their diseases or group of diseases

## **5. To promote and collaborate with European research projects**

The Network of European Rare Disease Federations will provide a forum to:

- Promote patient centred rare disease research priorities
- Disseminate information about rare disease research priorities and instruments

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<sup>1</sup> Declaration on Common Principles : [http://www.eurordis.org/article.php3?id\\_article=1296](http://www.eurordis.org/article.php3?id_article=1296)

- Exchange information on developing and managing research project or about partnering in research projects
- Identify best practices and disseminate them to bridge the gap between research and patients and empower their capacities to be active players

## 6. To participate in other relevant EURORDIS activities

Other relevant activities may include:

- European Public Affairs activities
- EurordisCare surveys
- Eurordis surveys on Orphan Drug Availability

The Network of European Rare Disease Federations will inform EURORDIS about new actions to be developed and will promote the implementation of European decisions. It will help EURORDIS to focus the efforts according to the real needs of patients with rare diseases.

### Organisation:

The **Network of European Rare Diseases Federations** will gather European Rare Disease Federation members of EURORDIS. These Federations are legal entities, incorporated, with patient associations as members. They can be either full or associate members. There are no additional criteria proposed. To continue to be a member of the European Network, the European federations need to pay their annual EURORDIS membership fees, to participate regularly in the activities of the European Network and respect these Terms of Reference.

**The Network will be coordinated by a Council of European Rare Disease Federations. The Council will be made up of representatives of European Federations of EURORDIS.**

The **representative** is the contact person for EURORDIS, and must be committed to attending all Council Workshops (face to face or conference calls) and to reply to emails. Each European Federation can appoint a representative and an alternate. It is the responsibility of the representative to keep its alternate up-to-date on all Network activities.

Other RD Federations who are not yet legally incorporated, or which exist as informal networks can participate in the Council and Network as **Observers**.

The Council of European Rare Disease Federations will hold at least one **Annual Workshop of the European Network**. Workshops will take place in different countries over time.

Additional Council meetings may be organised in Brussels or Paris throughout the year.

A dedicated **Web Section** will be created on the EURORDIS Website with all relevant information on the European Network, a mailing list, a blog and wikis, as necessary.

A **leaflet** will be created to promote and raise the visibility of the European Network.

## General financial guidelines

Eurordis will cover the cost of the yearly Workshop of the Council of European Networks of European RD Federations or of meetings of the Council in Brussels or Paris, including expenses such as: preparation, meeting room, equipments, coffee-break, lunch.

For the first meeting in May 2009, EURORDIS covered travel and accommodation expenses for one representative per European Federation invited to the Council Workshop. For the following years, travel and accommodation expenses will be covered by EURORDIS depending on financial capacities. EURORDIS will explore all possibilities to help cover expenses for the federations which cannot afford, based on fellowships covering all or part of expenses.

With the support of:



## **European Public Affairs Committee Rules of Procedure**

### **Adoption**

These rules of procedure for members of the European Public Affairs Committee (EPAC), including the Board of Directors, were first adopted by the Board of Directors on 27<sup>th</sup> March 2004, revised on 24<sup>th</sup> July 2006 and on 23<sup>rd</sup> November 2013.

### **Mandate**

EPAC is a committee of EURORDIS and EPAC members have an official permanent mandate to represent EURORDIS.

### **Purpose**

The purpose of EPAC is to voice the viewpoint of rare disease patients and, specifically:

- To share information in order that EPAC members have the same up-to-date level of information
- To discuss views and seek support from other colleagues
- To determine the EURORDIS position on relevant matters.

### **Objectives**

The objectives of EPAC are to ameliorate the quality and consistency of EURORDIS' policies and priorities as well as to expand EURORDIS' outreach in order to improve European rare disease policies.

EPAC seeks to attain these objectives by:

- Improving the exchange of information between EURORDIS' representatives,
- Empowering EURORDIS' representatives through proper background information and clear understanding of issues,
- Better supporting EURORDIS' representatives,
- Strengthening internal organisation,
- Conveying adequate information to our constituencies and stakeholders,
- Involving more people from the rare disease network.

### **Composition**

Members of EPAC are appointed by the EURORDIS Board (Board of Directors or Board of Officers), or if urgent, directly by the President in conjunction with the CEO and other concerned people in the team.

The membership comprises:

- All members of the Board of Directors,
- Staff and volunteers involved in EURORDIS advocacy activities,

- Immediate past Board members who still have a mandate to represent EURORDIS in an organisation or committee, or who are invited to continue contributing their expertise through EPAC.

The composition of EPAC is updated on an on-going basis. Appointments are for a defined period linked to the duration of their mandate in EURORDIS or external institutions.

The composition of EPAC is made available publicly on the EURORDIS website.

### **Rules of procedure**

- 1 The EPAC member should have prior consultation with the President and/or CEO and other relevant senior staff through the European Public Affairs Manager (Ariane Weinman) before going to important meetings or on issues important to EURORDIS, e.g. major policy positions or financial decisions.
- 2 When personally invited directly to speak on behalf of EURORDIS at a workshop, conference or any meeting of public importance, the EPAC member must first seek agreement from the President or the CEO, who can decide to appoint another representative. The contact is made through European Public Affairs Manager (Ariane Weinman)
- 3 EPAC members attending meetings should refer to themselves as representing EURORDIS as well as their national or international association (if applicable).
- 4 At each meeting/conference the EPAC member makes their best effort to reflect patients' viewpoints through proper internal consultation and to represent and defend the EURORDIS position and strategy.
- 5 Notwithstanding this, the EPAC member has a full mandate to speak on behalf of EURORDIS and to take 'on the spot' decisions if necessary, to the best of his/her knowledge with a wise sense of limits with regards to EURORDIS mission, values and positions.
- 6 Each EPAC member agrees to share important news and send a brief report of any meeting attended in a EURORDIS capacity directly to EPAC, send relevant documents for filing at EURORDIS, alert members when there is a need to read and take action and by whom and send details of any new contacts to the European Public Affairs Manager.
- 7 EPAC works almost exclusively through emails and exceptionally through conference calls and face-to-face meetings.



**Roles and responsibilities of  
EURORDIS Patient representatives (members and observers)  
in the Committee for Orphan Medicinal Products (COMP)**

Legislation (Regulation (EC) N° 141/2000 and Directive 2004/27/EC) provides for patient membership in the Committee for Orphan Medicinal Products (COMP) amongst other scientific committees.

EURORDIS, who actively participated in the development and implementation of the Orphan Medicinal Products Regulation, would like to ensure that rare disease patients are represented by full EURORDIS members (two members) at the COMP.

This document clarifies the roles and responsibilities of the EURORDIS representative within the European Medicines Agency's Committee.

**General role:**

In addition to the general work performed by each COMP member (see documents attached for details), the EURORDIS patient representative (in collaboration and with the support of EURORDIS) is expected to:

**Role:**

- Represent patients interests and provide a patient or "parent of patient perspective" view, on behalf of those directly affected by regulatory decisions
- To liaise with EURORDIS on a monthly basis by providing feedback from the COMP meetings

**Scope of the work:**

- Collaboration is crucial between the representatives (members and observers)
- Liaise with EURORDIS by:
  - Participating actively in the EURORDIS Therapeutic Action Group monthly conference call and annual meetings.
  - Sending a brief report or communicating during the monthly calls on each Committee for Orphan Medicinal Products meeting and conferences
  - Being closely involved in EURORDIS activities related to therapeutic development
  - Participating, upon availability, in the Drug, Information, Transparency and Action (DITA) Task Force
- In the review of applications and contribution to policy and guidelines, you are expected to:
  - Bring experience of the disease and/or identify patients with experience of the disease when necessary
  - Raise ethical issues during the discussion; identify ethical risk factors, propose risk prevention and minimisation measures
  - Identify potential topics which may require or benefit from additional patient consultation
- Actively contribute to patient information and communication material related to medicines, disseminate Committees' outcomes when they become public; pass on information to patients and patients' organisations
- Be prepared to participate or speak in other meetings and conferences
- To promote the European Regulation and the results of its implementation

**Mandate**

- 3 years, renewable

## Time Commitment / Workload

4-5 days/month (2-3 in London, 2-3 homework) plus about 8 additional days of travel per year.

- Time in COMP meetings:
  - 2-3 days/month in London
  - additional meetings in London may be organised.
- Homework: we estimate about 4-5 days/month of work to prepare and follow up the meetings. EMA estimates 150-200 applications for orphan designation per year and 50-100 applications for protocol assistance per year. Patients' representatives are expected to have an opinion on all dossiers, but not necessarily a scientific opinion as their main role is to introduce the patients' perspective.
- **Capacity-building opportunities:** approximately 8 days/year
  - Participation in the annual EURORDIS Membership Meeting, the European Conference on Rare Diseases and occasionally the EURORDIS Round Table of Companies Workshops.
  - Participation in national meetings (e.g. national rare disease alliances) or international meetings (e.g. DIA Euromeetings and forums, EPPOSI, TOPRA...)
  - Participation in training and capacity-building opportunities (e.g. DIA tutorials, EURORDIS Summer School, EUPATI training)

## Confidentiality and Conflicts of Interest

- All patients' representatives are expected to comply with the EMA for full confidentiality and declaration of potential conflict of interest
- Patients' representatives in the committee are identified, selected and nominated by EURORDIS and appointed by the European Commission on behalf of EURORDIS.
- However, it is EURORDIS policy that patients' representatives maintain their double affiliation when presenting themselves (i.e. EURORDIS and their own patients' organisation)
- As a consequence patients' representatives must declare their potential Conflicts of Interests at three levels:
  - i) those of EURORDIS (provided by EURORDIS)
  - ii) those of their own patient association provided by the President of the association and
  - iii) their own personal Conflicts of Interests as individuals.

All Declarations of Conflict of Interest should be submitted concurrently to EMA and EURORDIS.

## Conditions

- All meetings are on week days, other meetings by EURORDIS can be on weekends
- Member:
  - The travel and accommodation expenses are covered by the EMA
  - The member receives a daily allowance to cover your extra expenses in London, when travelling for the Committee for Orphan Medicinal Products.
- Observers
  - The travel and accommodation expenses are covered by EURORDIS
  - Under the current EMA policy, observers do not receive any daily allowance according to the EMA policy.
- Your travel and accommodation expenses are covered by EURORDIS or the conference organiser, when travelling for EURORDIS on agreed assignments. The rules of EURORDIS must be respected (i.e. agreement on cost of travel and accommodation) and EURORDIS reimbursement claim forms must be used.

## Profile

- Must belong to a rare disease patient organisation that is a full member of EURORDIS (preference is given to patients or parents of patients)
- Based in the European Union
- Available to travel to London 3 days/month plus a few other travel assignments
- Fluent English is compulsory (spoken and written)





## Terms of Reference

# EURORDIS Social Policy Action Group (SPAG)

Following the end of the mandate of the Social Policy Advisory Group (2015-2018), EURORDIS is launched the Social Policy Action Group, in April 2019.

**The EURORDIS Social Policy Action Group (SPAG) is an action group of volunteer patient advocates who disseminate and contribute to the positions of EURORDIS and its members, advocating for holistic and integrated care for people living with a rare disease and their families.**

## 1. Background

The Social Policy Action Group was preceded by the Social Policy Advisory Group, active from 2015 to 2018, with a mandate focused on "informing on patients' and families' social challenges and advising on social policy, provision of social care and related issues, guaranteeing the formulation of patient-centric approaches to the different social challenges".

The work of the Social Policy Advisory Group directly supported these important milestones for the rare disease community:

- The elaboration of the EURORDIS Position Paper "Achieving Holistic Person-Centred Care to Leave no One Behind: a contribution to improve the everyday life of people living with a rare disease and their families" (2019);
- The first [Europe-wide survey on the everyday and social impact of rare diseases](#): "Juggling care and daily life: The balancing act of the rare disease community" (2017), conducted by EURORDIS<sup>1</sup>;
- The work of EURORDIS within the EU-funded [INNOVCare project](#), focused on integrated health and social care for rare diseases, leading to good practice and advocacy outcomes (2015-2018);
- The elaboration of scientific publications on integrated and holistic care for rare diseases: [Client Group Rare Diseases](#) in Handbook Integrated Care (Castro R. et al.; 2017); [Bridging the gap between health and social care for rare diseases: key issues and innovative solutions](#) in Rare Diseases Epidemiology Handbook (Castro R. et al. 2017).

Building on these robust data, positions and good practices, the Social Policy Action Group is now launched, with a mandate focused on dissemination and advocacy.

## 2. Mission and objectives

**The SPAG is an action group of volunteer patient advocates who disseminate and contribute to the positions of EURORDIS and its members, advocating for holistic and integrated care for people living with a rare disease and their families.**

<sup>1</sup> Survey of over 3000 people living with a rare disease and family carers, conducted through the EURORDIS survey initiative [Rare Barometer Voices](#) and in the scope of the EU-funded [INNOVCare project](#).

**More specifically, the mission of the SPAG focuses on the following objectives:**

1. **Raising awareness** of the everyday needs of people living with a rare disease and their families;
2. **Advocating** for policies and services that address these unmet needs, at European level and at national and regional levels;
3. **Empowering** their patient organisations and the rare disease community to advocate for holistic and integrated care for people living with a rare disease and their families.

### 3. Commitments

**SPAG members:**

- Adhere to the [EURORDIS Volunteer Charter](#), adopted by the EURORDIS General Assembly on 8 May 2014 in Berlin;
- Agree to these specific Terms of Reference;
- Commit to liaising with their organisation in order to provide the position of their organisation on the topics to be addressed and to inform their organisation about the activities of the SPAG.

**Furthermore, the SPAG members commit to:**

- Attend a minimum of 3 SPAG update online calls each year;
- Present at a minimum of 5 national or European events per year: disseminating the advocacy messages included in the documents mentioned in section 1-Background;
- Elaborate 1 annual report (2 pages) to monitor the implementation of EURORDIS Position Paper in their country;
- Translate short summaries of key advocacy position documents;
- Contribute to other relevant dissemination and advocacy activities on holistic care.

**When taking part in conferences:**

- If not on behalf of the EURORDIS-SPAG: SPAG members shall make clear that the views expressed are their own views and not those of EURORDIS and the SPAG;
- If invited as a EURORDIS-SPAG representative: SPAG members must inform the EURORDIS contact person who will appreciate whether it is appropriate for a SPAG member to participate and represent the SPAG. When this is the case, the SPAG member shall ensure that the views expressed are those of the SPAG and identify her/himself both as EURORDIS as well as with her/his affiliated patient organisations.

The SPAG will communicate mostly via email and conference calls.

### 4. Composition

**The SPAG is composed of 8 to 12 patient advocates**, from several European countries and representing a diversity of rare diseases. Membership is voluntary.

**The members of the SPAG are nominated for a term of 3 years, from April 2019 to March 2022.**

**Profile of the SPAG members:**

- Patient, relative of patient or patient representative at a patient organisation (i.e. staff, volunteer);
- Fluent in English;
- Experienced/knowledgeable in one of the following topics: integrated and holistic care, social policy, social services;
- Experienced in participating in international and national conferences/committees on public health/social policy.

## 5. Contact and role of EURORDIS

The SPAG will be coordinated and assisted by Raquel Castro, Open Academy Director, Social Policy Director: [raquel.castro@eurordis.org](mailto:raquel.castro@eurordis.org); +34 93 220 32 24.

### EURORDIS shall:

- Coordinate the work of the SPAG;
- Provide technical and scientific support;
- Organise meetings of the SPAG, ensuring timely circulation of meeting documents;
- In relation with a SPAG member, EURORDIS will assist in the preparation of the agenda and minutes of the SPAG meetings;
- Contribute to the identification of the experts.

## 6. Useful Information

- [EURORDIS web site section on Social Policy and Integrated Care](#) (2018)
- [Results of the EU-funded INNOVCare project](#) (2018)
- [EURORDIS Answer to the EC Consultation on the European Pillar of Social Rights](#) (2016).



### 3.3.1.

20 April 2009

Doc. Ref. EURORDIS/mandate-TF/2009

## GENERAL TERMS OF REFERENCE FOR EURORDIS TASK FORCES

### Mandate, Objectives and Rules of Procedure

#### 1. GENERAL OBJECTIVE

The EURORDIS Board of Officers endorsed, at its 20 April, 2009 meeting, the creation of a general Task Force document describing the strategy and rules of procedure for the EURORDIS Task Forces. The aims of the task forces include providing support for the activities of the EURORDIS representatives in the Scientific Committees and Working Parties at the European Medicines Agency (EMA), sharing the expertise gained by staff and patient representatives in EMA Scientific Committees with other EURORDIS members, prepare other patient representatives to play leadership role in representing EURORDIS in EMA Scientific Committees, Working Groups and Ad Hoc Procedures and to perform the tasks described below.

As of 2009, EURORDIS is in the unique position of having eight patient representatives participating in the four committees and working parties (listed below) at the EMA and as such can therefore speak with a united and strong voice on drug-related issues.

The EURORDIS task forces are the Drug Information, Transparency and Access Task Force (DITA TF), Orphan Drug Task Force (ODTF), Paediatric Drug Task Force (PDTF) and possibly Gene & Cell Therapy Task Force. These groups of volunteers provide recommendations on all matters of direct or indirect interest to patients in relation to medicinal products to their representatives at the Patient and Consumer Working Party (PCWP); the Committee for Orphan Medicinal Products (COMP); the Paediatric Committee (PDCO); and the Committee for Advanced Therapies (CAT) respectively.

#### 2. MISSION

Specific activities for each task force will be regularly defined by the task force itself as well as in relation to the work of the Scientific Committee the task force is supporting.

The responsibilities of the EURORDIS Task Forces include the following:

- Commitment, Communication and Contribution
- Membership of a task force implies a commitment to participate actively in the work
- To advocate so as to contribute to the development and implementation of new Community Legislations in their respective working areas
- To contribute to increasing awareness of patients in relation to the development authorisation and use of medicines via the participation of the EURORDIS patient representatives in the committees and working parties.
- Review the implementation guidance documents issued by the EMA;



- To provide general advice in relation to product-specific matters – excepted confidential information;
- To propose ways to improve the transparency of the provision of information (i.e. information released by EMEA and national competent authorities, national applications and mutual recognition procedure)
- Participate in the collection of information on access to medicinal products (i.e. compassionate use prior to the marketing authorisation, and at the time of placing on the market)

The above list is provided as an indication of general activities that could be undertaken by each task force.

### 3. COMPOSITION of Task Forces

The task forces will be composed of the following representatives:

- Full and Associate Members of EURORDIS as well as Individuals (patients, parents, scientific or medical experts) who fulfil the following criteria:
  - availability
  - interest in medicinal product development and regulatory processes
  - English skills
  - interest for a specific rare disease with capacity to work on a larger set of diseases
  - patients and carers would be preferred as representatives, where possible
- Representatives from EURORDIS staff.

The final composition of the task force will be of a **maximum** of 15 members.

As members will represent themselves, it is their responsibility to liaise with their organisation as necessary in order to provide the position of the organisation on the topics to be addressed. It is also their responsibility to inform their organisation about the activities of the task force.

Members of the task force will be nominated for a term of **3 years** however membership will be confirmed on a **yearly basis** based on participation and commitment.

As a general rule, the discussion within the task force will not be subject to confidentiality, except for exceptional circumstances that will be clearly stated.

### 4. MEETING FREQUENCY

EURORDIS aims to organise a one-day face-face session once ( $\pm 1$ ) per year for each task force in accordance with EURORDIS' action plan. The meeting place and date will be decided on a case by case basis. Expenses will be covered as much as possible.

The meetings will be held in English.



## 5. CONTACT

The task forces will be co-ordinated by Maria Mavris (Drug Development Programme Manager), and led by representative member of staff and representatives in EMEA committees: DITA- François Houÿez and Lise Murphy; Orphan Drug – Maria Mavris and Birthe Holm; Paediatric Drug – Maria Mavris and Tsveta Schyns; Gene & Cell Therapy – Fabrizia Bignami and Michele Lipucci di Paola.

EURORDIS shall:

- Provide technical and scientific support to the task force.
- Provide regulatory and scientific support to the task force, when necessary.
- Assist in the co-ordination of the work of the task force.
- Organise meetings (face to face, conference call, video conferences) of the task force ensuring timely circulation of meeting documents;
- To provide information concerning the regulatory procedures applicable to orphan and non-orphan drugs
- Ensure adequate co-ordination of the work carried out within the task force;
- In relation with a task force member, will assist in the preparation of the agenda and minutes of the meetings of the task force;
- Contribute to the identification of experts;
- To review existing communication tools and evaluate possibilities for new ones;

## 6. GUARANTEES of INDEPENDENCE and PREVENTION OF POTENTIAL CONFLICTS OF INTEREST

6.1. The members of the task force shall not have any direct interests in the pharmaceutical industry, which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of potential conflicts of interest. These declarations will be made on a EURORDIS template document using the same format of document as the ones submitted to EMEA.

6.2. The patients' organisations to which the members of the task force belong shall fulfil the criteria approved by the EMEA Management Board on 24 September 2005 (EMEA/14610/04) except for the geographic expansion (national organisations are accepted).

These matters on independence and prevention of potential conflict of interest will be followed carefully and taken very seriously by EURORDIS as they should by each member of task forces. The overall credibility of EURORDIS to represent patients at EMEA is at stake. In these matters

## 7. CONFERENCES

When participating in international or other forums not specifically on behalf of the task force, members shall make clear that the views expressed are **their own views** and not those of the task force.

A member of the task force may participate in international or other forums and represent the task force, upon request or official agreement of the EURORDIS contact person for its task force.



In this case the task force member:

- **Shall ensure** that the views expressed are those of the task force.
- Will identify her/himself with its affiliations to her/his patient groups as well as to EURORDIS

The final decision whether or not it is appropriate for a member to participate and represent the task force will rely entirely on EURORDIS management (President and CEO).





07 12 2017

Doc. Ref. EURORDIS/mandate-HTATF/2017

## TERMS OF REFERENCE FOR THE EURORDIS HTA TASK FORCE

The EURORDIS Board of Directors endorsed, at its 07 December, 2017 meeting, the creation of a specific Task Force and approved the Terms of Reference describing the strategy and rules of procedure for the EURORDIS HTA Task Force.

### Objectives, Mandates, and Rules of Procedures

#### 1. GENERAL OBJECTIVES

The Task Force advises EURORDIS on all aspects regarding Health Technology Assessment policies and procedures. Its role is to inform EURORDIS on how health technologies are assessed at the national level, how patients are involved in these assessments and share views on the future European Cooperation on HTA.

The Task Force is composed of EURORDIS members who participated in HTA procedures in their respective countries.

The aims of the Task Force include:

- Raising awareness of the members on the utility and the benefits of HTA;
- Facilitation of the participation of patients in HTA procedures by sharing and collecting contributions from patients and their organisations, comparing different methods for the involvement of patients;
- Information on all issues on HTA, at national and European level, including the latest progress of EU cooperation on HTA (the technical and scientific part (EUnetHTA) and the political and strategic part (HTA Network));
- Contribution to consultations by the European Commission or other EU institutions;
- Contribution to EURORDIS positions;
- Analysis of and contribution to HTA activities (mapping of HTA activities, guidelines development, horizon scanning, early dialogues, parallel EMA/HTA scientific advice, scouting, assessment (joint and collaborative), national uptake...).

#### 2. MISSION

Specific activities for the HTA Task Force will be regularly defined by the Task Force itself.

The responsibilities of the HTA Task Force include the following:

#### **Commitment, Communication and Contribution.**

Membership of a Task Force implies a commitment to:

- Participate actively in the work;
- Propose ways to improve the transparency of the provision of information (i.e. information released by EUnetHTA and national HTA agencies);
- Contribute to the development and implementation of new Community Legislation and guidance in health technology assessment;



- Participate in the collection of information on published HTA reports.

The above list is provided as an indication of general activities that could be undertaken by the HTA Task Force.

### 3. COMPOSITION of the HTA TASK FORCE

The Task Force will be composed of the following representatives:

Full and Associate Members of EURORDIS who fulfil the following criteria:

- availability for six e-meetings and two face-to-face meetings per year
- interest in medicinal product development and health technology assessment, as document by prior experience such as:
  - participation in an HTA Early Dialogue (European or national level) or parallel EMA/HTA Scientific Advice
  - participation in the assessment of a health technology at national or European level
  - participation in an appraisal procedure at national level
  - EURORDIS Summer School / EUPATI
- English skills
- Patients and carers would be preferred as representatives, where possible

And representatives from EURORDIS staff.

The composition of the HTA Task Force will be of a **maximum** of 12 members.

As members will represent themselves, it is their responsibility to liaise with their organisation as necessary in order to provide the position of the organisation on the topics to be addressed. It is also their responsibility to inform their organisation about the activities of the Task Force and their own membership.

Members of the Task Force will be nominated for a term of **3 years** however membership will be confirmed on a **yearly basis** based on participation and commitment.

As a general rule, the discussion within the Task Force will be subject to confidentiality, except for exceptional circumstances that will be clearly stated.

### 4. MEETING FREQUENCY

EURORDIS aims to organise a one-day face-face session twice (2) per year in accordance with EURORDIS' action plan. The meeting place and date will be decided on a case by case basis. Expenses will be covered as much as possible.

The meetings will be held in English.

### 5. CONTACT

The HTA Task Force will be co-ordinated by Matteo Scarabelli (HTA Patient Engagement Manager).

EURORDIS shall:

- Provide technical and scientific support to the Task Force;
- Provide regulatory and scientific support to the Task Force, when necessary;



- Assist in the co-ordination of the work of the Task Force;
- Organise meetings (face to face, conference call, video conferences) of the Task Force ensuring timely circulation of meeting documents;
- Ensure adequate co-ordination of the work carried out within the Task Force;
- In relation with a Task Force member, will assist in the preparation of the agenda and minutes of the meetings of the Task Force;
- Contribute to the identification of experts;
- Review existing communication tools and evaluate possibilities for new ones.

## **6. GUARANTEES of INDEPENDENCE and PREVENTION OF POTENTIAL CONFLICTS OF INTEREST**

6.1. The members of the Task Force shall not have any direct interests in the pharmaceutical industry, which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of potential conflicts of interest. These declarations will be made on a EURORDIS template document using the same format of document as the ones submitted to EMA.

6.2. The patients' organisations to which the members of the Task Force belong shall fulfil the Rules for Eligibility to Participate in HTA approved by the Patients' and Consumers' organisations of the HTA Stakeholder Pool on November 2017.

These matters on independence and prevention of potential conflict of interest will be followed carefully and taken very seriously by EURORDIS as they should by each member of Task Force. The overall credibility of EURORDIS to represent patients at EMA or at EUnetHTA is at stake.

## **7. CONFERENCES**

7.1. When participating in international or other forums not specifically on behalf of the Task Force, members shall make clear that the views expressed are their own views and not those of the Task Force.

7.2. When being invited as a EURORDIS' representative, member of the EURORDIS Task Force on HTA, the member must inform the EURORDIS contact person who will appreciate whether it is appropriate for a member to participate and represent the Task Force.

In this case the Task Force member:

- Shall ensure that the views expressed are those of the Task Force.
- Will identify her/himself with its affiliations to her/his patient groups as well as to EURORDIS.

## **8. EURORDIS VOLUNTEER CHARTER**

The members of the EURORDIS Task Force on HTA complies with the [Charter](#) of the EURORDIS Volunteers, which has been adopted by the EURORDIS General Assembly on 8 May 2014 in Berlin.



## **Job Description**

Position **RareConnect Volunteer Moderator**

Team **Operations, Projects and Programmes**

### Description of time commitment

This depends on many factors including: the number of active moderators, the time since the community has been launched, the number of members in the community, and if there is high participation regarding a certain topic. On average many moderators spend 15 minutes on their tasks per week or about 1 hour per month.

## **About EURORDIS**

The European Organisation for Rare Diseases, EURORDIS, is a patient-driven alliance of patient organisations and individuals active in the field of rare diseases.

EURORDIS's mission is to build a strong pan-European community of patient organisations and people living with rare diseases, to be their voice at the European level, and to fight against the impact of rare diseases on their lives.

Created in 1997, EURORDIS is today a leading Health International Non Governmental Organisation (INGO) and is recognised as the largest European Rare Disease Patient Organisation. In 2012, EURORDIS has 544 members in 49 countries, 120 volunteers, 25 staff persons in Paris and Brussels and a budget of 3 million €. It has steadily growing and well balanced revenues both from the public sector (European Commission, national authorities) and the private sector (patient groups membership fees and grants, corporate sponsorship, foundation grants, event fees).

EURORDIS has an outreach to 1600 patient groups and works closely with the European Commission, the European Parliament, leading pharmaceutical and biotech companies and European research networks. EURORDIS, plays an essential role in the development and in decision making process in the areas of orphan drugs and advanced therapies, specialised hospital centres of care and their European networks, research activities and national strategies on rare diseases. EURORDIS coordinates the annual Rare Disease Day and manages a platform of web sites and social media communication tools.

## **Main scope of the post**

RareConnect is an online social network (available at [www.rareconnect.org](http://www.rareconnect.org)) whose aim it is to promote global conversation and collaboration to improve the lives of rare disease patients. A joint initiative of EURORDIS, the European Organisation for Rare Diseases, and NORD, the National Organization for Rare Disorders (USA) the project was launched as a pilot in 2009 as Rare Disease Communities and renamed as RareConnect in 2012. The initial goal is to create disease-specific online patient communities that enable patients to obtain valuable information about their disease, share experiences, find disease-specific organizations, and network globally. Each community is built in co-operation with respective EURORDIS and NORD member patient groups active in a

specific disease area. The long-term plan for this project is to expand the platform and its capability to connect larger numbers of patients globally, with the objective of supporting clinical trial recruitment and outcomes management, while also increasing knowledge and understanding of rare diseases.

EURORDIS has worked with NORD to complete a strategic plan to expand and enhance the RareConnect Online Patients Communities Project. The RareConnect volunteer moderator is an active participant in the implementation of various aspect of that process.

The RareConnect volunteer moderator works with the Online Community Managers to:

- Support the construction and animation of a community.
- Ensure quality information is shared on the community based on the Online Communities Charter.
- Promote good practise community support.

Specific tasks include, in particular, but not limited to:

- Participate in the creation and set up of a new community with other moderators by providing information from your country and patient group to the RareConnect team.
- Publicise and promote the community within national patient group by ensuring a link to the community is added on patient group website and in communication materials.
- React appropriately to new stories, comments, or forum posts added to the community after receiving an email notification.
- Provide emotional support and a sympathetic listening ear to members in need of an outlet to share their personal journey of living with a rare disease.
- Respond to a member's need for information by supplying a link to a trusted resource, scientific publication, or patient group publication where appropriate.
- Update patient group on progress and activity on the RareConnect community while keeping the RareConnect team updated on the patient group's activities.
- Suggest new content (articles, stories, videos) to the RareConnect team.
- Update the community on their activities by posting Stories.
- Send a welcome message through a private message to new members identifying themselves and their patient group.
- Encourage contributions from other members by posting questions, new research updates, or information on treatments from trusted sources
- Correct translations that have been done by translation company, but may be missing the correct rare disease term.
- Ask questions about security, share concerns they might have, and report any incidents to the RareConnect team.
- Participate in webinars and provide feedback on the community and web tool to RareConnect team.

**Profile:**

Essential:

- English speaker, knowledge of second European language
- Direct experience living with a rare disease
- Knowledge of using social networks

Preferred:

- Representative of patient organisation
- Interested in working with other international patient groups

# Patient Voices Programme Advisory Committee

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## **GENERAL OBJECTIVE**

The Patient Voices Programme Advisory Committees constitute a group of expert individuals from a range of backgrounds (academia, corporate and policy) providing advice on the approach in capturing the voice of patients and their representatives in an easy, streamline and efficient manner to ensure the inclusion of the patient perspectives in the policy and decision making processes.

The Patient Voices Programme Advisory Committees should be instrumental in:

- (a) providing expert opinion and input the overall strategy of the Programme
- (b) providing expert opinion and input on identifying policy area priorities that will benefit from patient perspectives
- (c) providing expert opinion and input on methodological aspects of the survey to reach the highest standard of relevance
- (d) being an active link and developer of partnership with key stakeholders
- (e) appointing the members of the ad-hoc advisory committee members in synergy with the Steering committee members in order to provide appropriate guidance on specific topics

## **COMPOSITION AND SELECTION CRITERIA**

A group of experts with diverse backgrounds in academic research, health and survey sectors corporate and health relate policy experts.

The Members should cover a broad range of scientific and technical expertise in order to provide up-to-date knowledge and sound advice in supporting the mission and strategy of Patient Voices Programme. The individual members' expertise can be specialised as well as transversal.

The role of the Advisory Committee will be to provide advice and opinions with no decisional power, which will remain in the remit of the Steering committee.

The number of members of the Advisory Committee may vary according to the needs of Patient Voices Programme.

Experts will be appointed by the Patient Voices Programme Steering Committee for a mandate of 1 year, renewable for up to 2 mandates, at the discretion of the Steering Committee and the continued interest of the experts. The Steering Committee will ensure a certain level of constant renewal.



Acting members of the EURORDIS Board of Directors and staffs are automatically excluded from holding a position on the Patient Voice Programme Advisory Committee.

## **ORGANISATION**

The list of members will be made available on general communications about the Programme.

The members are not intended to meet regularly as a group; the interactions will be mostly performed through emails and phone calls (two or three time per survey) initiated, coordinated and chaired by the Programme leader.

The experts are a highly valuable resource to EURORDIS and will be valued for their significant in-kind support.

The members of the Patient Voices Programme Advisory Committees adhere to the CHARTER OF THE EURORDIS VOLUNTEERS (<http://www.eurordis.org/volunteering#tabs-2>)

# Patient Voices Programme

## Topic Expert Committees

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### **GENERAL OBJECTIVE**

The Patient Voices Programme Topic Expert Committees constitute a group of expert individuals with a diverse range of backgrounds (academia, corporate and policy) who serve to advise on the approach and methodology in capturing the voice of patients and their representatives in an easy, streamlined and efficient manner on transversal topics for which they are considered as experts by the rare disease community. A new Topic Expert Committee will be composed for each survey in the Programme. Individuals may serve on several Topic Expert Committees.

The Patient Voices Programme Topic Expert Committees should be instrumental in:

- (a) providing expert opinion on the overall strategy for gathering the patient perspective on a specific topic
- (b) providing input on methodological aspects of the Programme's surveys to reach the highest standard of relevance for a specific topic
- (c) providing expert opinion and input on the analysis of results to reach the highest scientific relevance for a specific topic
- (d) being an active link and developer of partnership with key stakeholders

### **COMPOSITION AND SELECTION CRITERIA**

A group of highly distinguished experts with diverse backgrounds in academic research, health and survey sectors, corporate and health related policy experts.

The Members should cover a broad range of scientific and technical expertise in order to provide up-to-date knowledge and sound advice in supporting the mission and strategy of the Patient Voices Programme. The individual members' expertise can be specialised as well as transversal.

The role of the Topic Expert Committee will be to provide advice and opinion with no decisional power, which will remain in the remit of the Steering committee.

The number of members of the Topic Expert Committee may vary according to the needs and current survey of Patient Voices Programme.

Experts will be appointed by the EURORDIS Patient Voices Programme Steering Committee. The Steering Committee will ensure a certain level of constant renewal.

Acting members of the EURORDIS Board of Directors and staff are automatically excluded from holding a position on the Patient Voices Programme Topic Expert Committee.

## **ORGANISATION**

The list of members will be made available on all general communication about the Patient Voices Programme.

The members are not intended to meet regularly as a group; the interactions will be mostly performed through emails and phone calls (at least once a year) initiated, coordinated and chaired by the Programme leader.

The experts are a highly valuable resource to EURORDIS and will be valued for their significant in-kind support.

The experts on the Patient Voices Programme Topic Expert Committees adhere to the CHARTER OF THE EURORDIS VOLUNTEERS (<http://www.eurordis.org/volunteering#tabs-2>)