



EURORDIS – Rare Diseases Europe By-Laws

April 2019

Contents

EURORDIS – Rare Diseases Europe By-Laws	4
1. Vision, Mission, Values & Ethics (revision adopted in November 2023)	4
EURORDIS' Vision	4
EURORDIS' Mission	4
EURORDIS' Organisational Statement	4
Organisational model	4
EURORDIS' Values	5
EURORDIS' Ethical principles	5
2. Objectives (Statutes Article 1 & 2)	8
EURORDIS' Headquarter & Offices	8
3. Membership (Statutes Articles 4 & 5) (Annex III)	9
Membership	9
Membership resignation, suspension or loss	10
4. Board of Directors (Statutes Article 6) (Annex IV) (revision adopted November 2022)	11
Board of Directors (Statutes Article 6)	11
Board of Directors Meetings (Statutes Article 7)	11
Board of Officers Meetings	13
5. Operational Entities (Statutes Article 11) (Annex V)	16
Councils (Annex V.a.)	16
Policy Committees (Annex V.b.)	16
Programme Committees (Annex V.c.)	16
Project Steering Committees (Annex V.d.)	16
EURORDIS Events Programme Committee (Annex V.e.)	16
6. General Assembly: Agenda & Overview of EURORDIS' operations (Statutes Article 12) (revision adopted April 2023)	17
Agenda	17
Oversight – Annual Activity Report and Work Programme	17
Electronic vote	17
Annexes	19
Annex I – Private Resource Development Policy (ongoing revision)	19
Annex I.a. EURORDIS Policy on Financial Support by Commercial Companies	19
Annex I.b. EURORDIS Guidelines & Protocol for Bilateral Meetings with Healthcare Companies	19
Annex I.c. EURORDIS Policy for Declaration of Interests and Confidentiality Agreements	19
Annex II – Human Resource Policy	20
Annex II.a. EURORDIS Internal Staff Rules	20

Annex II.b. EURORDIS Volunteer Charter	20
Annex III – EURORDIS Membership	21
Annex III.a. EURORDIS Membership criteria	21
Annex III.b. How to become a member	21
Annex IV – EURORDIS Board of Directors	22
Annex IV.a. Board Members’ Roles & Responsibilities	22
Annex IV.b. General Secretary and Deputy General Secretary Roles & Responsibilities	22
Annex IV.c. President & Vice-President Roles & Responsibilities	22
Annex IV.d. Treasurer Roles & Responsibilities	22
Annex V – Operational Entities	23
Annex V.a. Council Terms of References	23
Annex V.b. Policy Committees	23
Annex V.c. Programme Committees	23
Annex V.d. Project Steering Committees	23
Annex V.e. EURORDIS Events Programme Committee	23

EURORDIS – Rare Diseases Europe By-Laws

1. Vision, Mission, Values & Ethics (revision adopted in November 2023)

EURORDIS' Vision

EURORDIS' vision is a world where all people living with a rare disease can have longer and better lives and can achieve their full potential, in a society that values their well-being and leaves no one behind.

To achieve their full potential, people living with a rare disease need to be:

- Recognised as equal citizens with their rights fully respected
- Diagnosed timely and accurately
- Supported with state-of-the-art medical and social care, or cured
- Included in society in all aspects of life and enabled to live independently.

EURORDIS' Mission

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

EURORDIS' Organisational Statement

EURORDIS-Rare Diseases Europe is a unique, non-profit alliance of over 1,000 rare disease patient organisations from more than 70 countries that work together to improve the lives of all people living with rare diseases in Europe.

By connecting and mobilising all stakeholders from within and outside the rare disease community, EURORDIS strengthens the voice of people living with rare diseases and shapes research, policies and services.

Organisational model

EURORDIS is a Network Leverager within an Ecosystem of networks of member organisations, advocates, organisations at large, partners and stakeholders to change the game and achieve its strategic goals.

Within a new vibrant environment, which EURORDIS has contributed to building over the last 25 years, EURORDIS has redefined and focused its unique role in the rare disease ecosystem.

By 2030, EURORDIS will have catalysed and led impactful motivated networks of member organisations, and of advocates across diseases and borders – including young advocates. EURORDIS will enable the relay of PLWRD's needs and support the integration of European with national actions in key policy areas.

By 2030, EURORDIS will be recognised as a driver of change, with a unique role in initiating and leveraging networks of partners and stakeholders to exchange experience, co-produce knowledge and create synergies to achieve our strategic objectives.

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 equity**, EURORDIS is also guided by the following values:

- **People first** – EURORDIS puts people first and endeavours to do what's right for the people affected 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.
- **Authentic** – EURORDIS is **credible** in representing the voice of people living with rare diseases because its positions are based on contributions from its members, and on **evidence and experience** from a wide range of people living with rare diseases. EURORDIS is **trustworthy** and ensures that its representatives - volunteers and staff - are people who understand what it means to live with a rare disease.
- **Authoritative and Professional** - EURORDIS strives for excellence in all that it does and to represent the perspective of people living with rare diseases 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 rare diseases.
- **Courageous** – EURORDIS has a strong sense of integrity and is **forthright and persistent** in representing the needs, concerns, proposals and preferences of people living with rare diseases.
- **Innovative** – EURORDIS is a **visionary** organisation that is highly **entrepreneurial** in seeking out and implementing pioneering solutions that serve people living with rare diseases.
- **Collaborative** – EURORDIS recognises that common problems are often solved more effectively by finding synergies and promoting collective action. EURORDIS is **respectful** that many stakeholders can help improve the lives of PLWRD and therefore is open to collaboration with like-minded organisations that share its vision and goals.

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 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** 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 reflects 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 & 2)

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 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 4 & 5) (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.

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
- 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 6) (Annex IV) (revision adopted November 2022)

Board of Directors (Statutes Article 6)

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 between **12 to 15 directors**.

The number of directors 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 skills, age, gender, social and professional background, disability, ethnicity, 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 b) these declarations are reviewed collegially by the CEO, the Governance Senior Manager, and the Human Resources Director c) clearance or issues are discussed with the concerned 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 7)

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.

Ad-hoc Online Satellite Meetings are also regularly organised on specific topics to enable enough time for discussion on an advocacy policy, a main programme, a policy or a strategic priority (practice is usually 6 per year).

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 Board of Directors meeting;
- Information on the Table of Action & Decisions and Tracking Table of Actions & Decisions from Board of Officers Meetings

Information covers:

- Finance: Presentation of monthly cash flow, quarterly revised annual budget, year-end forecast; Presentation on financial performance; Information over financial operations and administrative policy or procedures on finance and administration adopted by Officers;
- Human Resources: overall presentation of the team chart, staff organisation with regards to mission and main tasks and latest decisions taken by the Board of Officers or the CEO;; Information over human resource policy and procedures adopted by Officers;;
- CEO report on advocacy matters, planning and programming of activities, implementation of previous Board's strategic discussions, general overview of projects,
- President's report on CEO performance review, compensation and discharge at least once every two years

Action covers:

- Membership applications (if the BoO considers the need), and periodic 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
- 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
- Annual Reports composed of Annual Activity Report, Annual Financial Report, Annual Audited Financial Statements and Auditors' Report
- Review Board performance and take regular steps to develop and improve this performance.
- Adopt the EURORDIS' by-laws which determine the application details of the Statutes
- 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 the chief executives (e.g. Chief Executive Officer, , Chief Operating Officer, Chief Financial Officer) and select the Chief Executive Officer

- Appointment, support and monitoring of the Chief Executive Officer
- Establishing operational entities for the purpose of assisting and providing advice in the context of EURORDIS specific activities, programmes or projects

Board of Officers Meetings

EURORDIS Board of Officers meets at least once every 3 months.

The established practice at EURORDIS is to hold between **4 to 6 Board of Officers meetings per year**. The Board of officers meets either by videoconference or face-to-face the day before the Board of Directors meeting.

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

Introduction covers:

- Review and approval of the Draft Agenda of the Board of Officers meetings
- Information on Board members;
- Pre-adoption of Minutes of previous Board of Directors meeting;
- Review and 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, financial situation, budget and forecast, closing of account, quarterly revised annual budget, year-end forecast; Presentation on financial performance; risk monitoring, Control over financial operations and administrative policy or procedures on finance and administration;
- Human Resources: Presentation and understanding of all changes in team chart, staff and volunteers situation and organisation with regards to mission and main tasks, recruitments, resignations or contract ending, job evolutions; Control and decision over new job position being created, adoption of job descriptions for new positions 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, overview and update on projects and programmes, report on fundraising policy and activities; overview on other key operational activities, follow-up and risk monitoring

Action covers:

- Membership applications, membership re-assessment, membership analysis
- Preparation of Annual General Assembly: agenda, documents, resolutions
- Preparation of Annual and Multi-Annual Work Programme
- Adoption of other administrative or financial or legal policies affecting public accountability
- Operational steering discussions on main advocacy issues, on new programmes or activities or events, and in-depth reporting to control their implementation
- Operational steering discussions on operational entities, their term of references, their composition, their activities
- Operational steering discussion on resource development, major initiatives, fund raising policies and practices
- Adoption of job descriptions for new position, except for the chief executives (e.g. CEO, CFO, COO) pre-adopted by the Officers but adopted by the Board of Directors
- Pre-adoption of governance documents (revision of bylaws)
- Preparation of main strategic discussions at the Board of Directors

- Preparation, review and pre-adoption of Agenda for the next Board of Directors meeting
- Selection of candidates submitted to official calls for candidates and appointment of permanent EURORDIS representatives in external entities or informed of the decisions taken by the Chief Executive Officer and the President

Role of the Board of Directors (Statutes Article 8)

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 is the strategic decision-making body**. It focuses on achieving the objectives of EURORDIS for persons living with rare diseases: the strategy, main programmes, overall organisation of members or volunteer entities as well as of staff and financial sustainability. The role includes:

- 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, overall strategic oversight, strategic discussions, orientations and decisions
- To ensure the good governance of EURORDIS.
- To adopt the annual reports (activity and financial)
- To review key policies prepared by the BoD and to provide input
- To adopt position papers and policies
- To manage controversial and reputational damaging issues
- 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.
- To select Officers from its members, by secret ballots, composed of a President, two Vice-Presidents, a General Secretary, a Deputy General Secretary, a Treasurer.
- To oversee the activities of the Board of Officers which report to it.

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 Advocacy Committee (ADVOC)

Role of the Board of Officers (Statutes Article 6 & 10)

The **Board of Officers** steers operational direction. It assists the President in the implementation of decisions or orientations of the Board of Directors.

The Officers are elected among the Directors by the Board of Directors, by secret ballots. All Officers are elected for a period of one year and eligible for re-election at the end of their terms.

The Board of Officers ensures oversight of financial and human resources, overview of programme/ projects and other key operational activities, follow-up and risk monitoring, organizational capacity and architecture, governance (review of elements of by-laws), approve membership applications, adopt the job descriptions of new

job positions, going into further details than the Board of Directors on financial matters, human resource matters, procedures, appointment of representatives or nomination of candidates. The Board of Officers is working in strong alignment with the CEO and the Core Leadership Team.

The Board of Officers:

- Ensure oversight of the financial situation, cash flow, budget and forecast, closing of accounts, risk monitoring, policies and procedures
- Draft, monitor and update the EURORDIS' by-laws which determine the application details of the Statutes
- Ensure the organisational basis (personnel and financial) of Eurordis is adequate to meet its operational needs: oversight of staff and volunteers situation, adoption of new job creation, understanding of changes made and of the organisational team chart, policies and procedures
- Overview of programmes / projects and other key operational activities, follow-up and risk monitoring
- Design and monitoring of the Organisational Capability and Architecture

Role and responsibilities of the members of the Board of Directors (Statutes Article 6) and Board of Officers

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 of Directors, 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 of Directors members' Roles & Responsibilities
- Board of Officers members' Roles & Responsibilities:
 - President's Roles & Responsibilities
 - Vice Presidents' Roles & Responsibilities
 - Treasurer's Roles & Responsibilities
 - General Secretary's and Deputy General Secretary's Roles & Responsibilities

5. Operational Entities (Statutes Article 11) (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)
- The Council of Disease Specific European Federations or Networks (CEF)

Policy Committees (Annex V.b.)

- The Therapeutic Action Group (TAG)
- The Drug, Information, Transparency & Access Task Force (DITA TF)
- The Health Technology Assessment Task Force (HTA TF)
- The Digital and Data Advisory Group (DAG)
- The Social Policy Action Group (SPAG)
- The European Patient Advocacy Groups for each grouping of rare diseases (ePAGs), linked to European Reference Networks and the Steering Committee (ePAGs SC)
- The Rare Cancer Advocates Network (RCAN)
- The Mental Health and Wellbeing Partnership Network

Programme Committees (Annex V.c.)

- Rare Disease Day Steering Committee
- Rare Disease Day Outreach Committee
- EURORDIS Open Academy Programme Committees

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.)

- Black Pearl Committee
- European Conference on Rare Diseases and Orphan Products (ECRD) Programme Committee
- EURORDIS Membership Meeting (EMM) Programme Committee
- EURORDIS Round Table of Companies (ERTC)

6. General Assembly: Agenda & Overview of EURORDIS' operations (Statutes Article 12) (revision adopted April 2023)

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 Programme, including Action Plan, Governance and Team Charts & 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 and Work Programme

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
- The Board of Directors members and Officers – as before the Annual General Assembly Meeting
- 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 Programme for the next year –Action Plan, Budget, Governance and Team 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.

Electronic vote

The vote is opened during the General Assembly and can be opened up to a date that is communicated to the Members at least one month before the General Assembly. The management of the electronic vote is delegated to a service provider with specialization in online voting

Full Members can vote during the General Assembly until the end of the period of the electronic vote that is indicated on the convocation.

Proxy vote is technically not possible for the online general assembly.

The convocation to the Annual General Assembly includes the email of the person who can receive and answer questions. This person also supervises the counting of the votes.

The results of the votes are published on the General Assembly webpage on EURORDIS website and disseminated to the Members through the newsletter.

General questions

Members can ask questions on meeting items to a specified email address that is communicated to them at least one month before the General Assembly in the convocation.

The questions will be answered at the General Assembly and on the webpage of the General Assembly.

Annexes

Annex I – Private Resource Development Policy

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

Annex I.b. EURORDIS Guidelines & Protocol for Bilateral Meetings with Healthcare Companies (ongoing revision)

Annex I.c. EURORDIS Policy for Declaration of Interests and Confidentiality Agreements (ongoing revision)

Annex II – Human Resource Policy

Annex II.a. EURORDIS Internal Staff Rules

Annex II.b. EURORDIS Volunteer Charter

Annex III – EURORDIS Membership

Annex III.a. EURORDIS Membership criteria

Annex III.b. How to become a member

Annex IV – EURORDIS Board of Directors

Annex IV.a. Board Members' Roles & Responsibilities

Annex IV.b. General Secretary and Deputy General Secretary
Roles & Responsibilities

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

Annex IV.d. Treasurer Roles & Responsibilities

Annex V – Operational Entities

Annex V.a. Council Terms of References

- CNA Terms of Reference
- CNA Common Goals & Mutual Commitments
- CEF Terms of Reference

Annex V.b. Policy Committees

- ePAG Constitution (adopted in November 2022)
- TAG (adopted in November 2022)
- SPAG Terms of Reference (adopted in November 2023)
- DITA – TF Terms of Reference
- HTA TF Terms of Reference
- DAG Terms of Reference
- The Mental Wellbeing Partnership Network (adopted in July 2023)

Annex V.c. Programme Committees

- Rare Disease Day Steering Committee
- Rare Disease Day Outreach Committee
- EURORDIS Open Academy Programme Committees

Annex V.d. Project Steering Committees

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

Annex V.e. EURORDIS Events Programme Committee

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- European Conference on Rare Diseases and Orphan Products (ECRD) Programme Committee
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- EURORDIS Round Table of Companies (ERTC)



P O L I C Y

EURORDIS POLICY ON FINANCIAL SUPPORT BY COMMERCIAL COMPANIES

March 2022

(5th Version: Initial 2001; Revised 2003, 2007, 2009, 2022)
A revision of this policy is planned for 2023-2024.

TABLE OF CONTENT

1	INTRODUCTION	3
1.1	About rare diseases.....	3
1.2	About EURORDIS	3
1.3	About EURORDIS funding.....	3
1.4	About EURORDIS Policy on Financial Support by Commercial Companies	4
2	GENERAL PRINCIPLES.....	6
2.1	Principles to be applied by EURORDIS in its relationship with Commercial Companies	6
2.2	Exclusion factors	7
3	Types of Financial Support by Commercial Companies to activities promoted by EURORDIS.....	7
3.1	Funding of EURORDIS projects	7
3.2	Funding of EURORDIS events	7
3.3	Funding of EURORDIS communication activities	8
3.4	Membership of the EURORDIS Round Table of Companies	8
3.5	One-off charitable donations.....	9
3.6	Other In-kind support.....	9
4	EURORDIS involvement in activities of the health industry	9
4.1	Promotional activities related to approved prescription medicines	9
4.2	Industry press releases	10
4.3	Training organised by industry or a group of companies.....	10
4.4	Participation in conferences or seminars held by industry	10
4.5	Individual compensation	10
4.6	Involvement in industry-source websites or other material.....	11
4.7	Diseases awareness campaigns by industry	11
5	Process	11
5.1	Documentation	11
5.2	Accountability	12
5.3	Recognition and visibility of the relationship	12
5.4	Transparency policy	12
5.5	Derogation.....	12
6	Final remarks	13

1 INTRODUCTION

1.1 About rare diseases

There are about 6,000 to 8,000 rare diseases affecting an estimated 30 million people throughout Europe. Most rare diseases are chronic, progressive, disabling, severe to very severe and most often life-threatening. While they mainly affect children, they can occur at any time in life. There is no treatment and no cure for most rare diseases.

1.2 About EURORDIS

The European Organisation for Rare Diseases, EURORDIS-Rare Diseases Europe *is a non-governmental patient-driven alliance of patient organisations and individuals active in the field of rare diseases, dedicated to improving the quality of life of all people living with rare diseases in Europe..*

EURORDIS represents more than 900 rare disease organisations in over 70 different countries. It is therefore the voice of 30 million patients affected by rare diseases throughout Europe.

It is supported by its members, the French Muscular Dystrophy Association (AFM), the European Commission, and corporate foundations and the health industry. EURORDIS was founded in 1997.

Further details concerning EURORDIS and rare diseases are available at: <http://www.EURORDIS.org>

EURORDIS' 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 - directly or indirectly - to fight against the impact of rare diseases on their lives.

To this end, EURORDIS undertakes activities on behalf of its members, notably in favour of:

- Empowering rare disease patient groups
- Advocating rare diseases as a public health issue
- Raising public rare disease awareness, and also that of national and international institutions
- Improving access to information, treatment, care, and support for people living with rare diseases
- Encouraging good practices in relation to these
- 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.

Amongst its major achievements, EURORDIS played a fundamental role in the adoption of the EU Regulation on Orphan Medicinal Products, the EU Regulation on Paediatric Use of Medicines, the EU Regulation on Advanced Therapies, as well as of the Commission Communication on "Rare Diseases: Europe's challenges" and the Council Recommendations on an action in the field of Rare Diseases. EURORDIS is taking an active role in the implementation of these regulatory and policy documents and will follow up closely on concrete achievements. This track record has been made possible thanks to EURORDIS legitimacy, credibility, strength of its network, as well as to its independence.

1.3 About EURORDIS funding

As any other organisation, EURORDIS needs funds to carry out its mission. When it was first established, EURORDIS was funded 100% by its members, in particular by AFM-Telethon, a major patient group. EURORDIS has gradually diversified its sources of funding from the European Commission and private sources. The European Commission supports EURORDIS activities through grants such as Research or Public Health grants. Private sources of funding include private foundations and commercial companies from the health and non-health sector.

Like many other patient organisations, EURORDIS is increasingly expanding the financial support it receives from commercial companies for a significant proportion of its activities and projects.

To maintain its independence, EURORDIS has set itself the objective to balance revenues, both monies and in-kind, from these 3 different sources in its Strategy 2010-2020. The ideal goal is to reach the following distribution: 1/3 from Patient Organisations including membership fees to EURORDIS, AFM-Telethon and the economic valorisation of volunteers contribution, 1/3 from the public sector including the European Commission (EC) and national authorities and 1/3 from the private sector including not-for-profit organisations and commercial companies, both from the health and non health sectors.

- (a) The annual planned maximum “health sector industry” funding shall be of 45% (+/-5%) of total budget excluding volunteers. As a result, our Health Sector industry will consistently be well below 50% of total income whether including volunteers or not.
- (b) EURORDIS will continue to include the Fair market value of volunteer contributions in its financial statements and ratios, recognizing the significant value contributed pro bono by the patient community
- (c) No single industry partner shall contribute more than 5% of total budget excluding volunteers

To avoid the risks inherent in a relationship between an NGO and commercial companies, and to avoid potential conflicts of interest, the following activities of EURORDIS are never funded by commercial companies of the health sector:

- All activities related to governance, mainly the Board meetings and the General Assembly;
- The salaries of the staff dedicated to advocacy work (mainly the CEO and the European Public Affairs Directors);
- All activities related to EURORDIS representation in different fora, such as the EMA Committees or the EU Committee of Experts on Rare Diseases.

1.4 About EURORDIS Policy on Financial Support by Commercial Companies

On the European political scene, EURORDIS is widely credited with being the voice of people living with rare diseases. EURORDIS has played a major role in creating a favourable framework for research development and access to treatments for people living with rare diseases (PLWRD). It is therefore bound to attract the attention of companies that have a particular interest in the development of treatments and other services for rare diseases patients. EURORDIS therefore felt the compelling need to establish clear rules to regulate its relationships with commercial companies.

Since 2000, EURORDIS has been at the forefront of the promotion of both good practices in the field of NGOs' Transparency and the regulation of relations between patient groups and commercial companies. This twofold goal has been mainly pursued at three levels:

1. The adoption in 2005 of the EURORDIS Position on NGOs Transparency (http://www.eurordis.org/IMG/pdf/Eurordis_position_transparency_oct05.pdf): Eurordis believes that transparency cannot be restricted to the narrow issue of transparency on funding - a necessary but not sufficient condition of transparency. Any policy on transparency should provide clear answers to the following questions: Who does the NGO represent? What is its representativeness? How is the NGO funded and which public or private interests does it represent? Does the NGO have a track record of credible work? Does the NGO really contribute to the debate? Does it have clear written public statements on its positions?

EURORDIS believes that the transparency of an NGO lies primarily in: its mission and values; the legitimacy of its membership base; its governance practices; and its internal and public policy practices. Consequently, the transparency of an NGO also lies in the transparency of its financial information; the internal and external financial control by independent audits; the transparency of its financial relationships with funding sources, both public and private; the transparency of its financial relationships with commercial companies; the prevention of potential conflicts of interest, both public and private.

In all of its activities EURORDIS respects and promotes the fundamental value of transparency, by following the principles of legitimacy, credibility, responsibility, independence and accountability.

2. The elaboration of the current EURORDIS Policy on Financial Support by Commercial Companies: this policy was initially adopted in 2001, and successively reviewed in 2003, 2007 and 2009; it does not set out to provide a definition of every possible funding opportunity or relationship, but rather to define a set of principles.

3. The contribution to the elaboration, in 2008-2009, of a Code of Practice between Patients' Organisations and the Healthcare Industry (http://www.eurordis.org/IMG/pdf/round_table_code_conduct.pdf).

EURORDIS believes it is essential to establish transparent rules about financial support from commercial companies, and in particular about what companies may - or may not - expect from EURORDIS in return.

The present Policy Paper covers issues related to financial support, in-kind support and involvement of EURORDIS in companies' activities. It is aimed at ensuring that EURORDIS' members, the general public and all relevant stakeholders are aware of the EURORDIS policy as validated by our Directors. EURORDIS directors, staff and volunteers are expected to adhere to this policy and to perform their duties accordingly.

This policy may be further reviewed when needed.

2 GENERAL PRINCIPLES

2.1 Principles to be applied by EURORDIS in its relationship with Commercial Companies

EURORDIS welcomes financial support by commercial companies as long as the relationship between EURORDIS and these companies is based on the following principles:

- relevance of a public health objective driven by patient needs
- full independence of EURORDIS
- mutual respect
- mutual benefit
- accountability and transparency

EURORDIS believes it is important to establish and maintain relationships with commercial companies in order to enhance communication between patients, whose interests we represent, and companies, whose decisions will affect the provision of health services or treatments to patients.

EURORDIS sees corporate donation programmes as a good practice in corporate governance and one of the ways commercial companies can support people affected by the rare diseases they are working on, or redistribute to the European rare disease community some of the profits they are making.

EURORDIS supports the availability of the widest range of orphan medicinal products, other medicines, treatments and health services; it does not endorse individual medicinal products or treatments; it encourages active partnership between patients and health professionals as well as discussion of all available options to ensure patients make informed choices.

The relationship between EURORDIS and commercial companies is based on partnership, while preserving EURORDIS independence and integrity. To ensure a successful partnership, each partner should learn to understand each other's internal culture and external constraints.

Financial support resulting from partnerships with companies is dedicated to activities in the areas of rare diseases; treatments; public awareness; patient support; capacity-building; and social, health and educational services.

In any case, funding by commercial companies:

- must be for the benefit of the patients EURORDIS represents,
- must not entail product advertisement,
- cannot influence in any way EURORDIS policy, positions or decisions, whether explicitly or implicitly.

As long as these principles are respected, EURORDIS does not foresee any potential conflict of interest with commercial companies at large, with the important exception of commercial companies in the health sector.

2.2 Exclusion factors

EURORDIS does not support any specific medicinal product, brand, or health service. It must not be – or appear to be - associated with any specific commercial company.

EURORDIS refuses financial support from companies generating a public health risk, making unsubstantiated or misleading claims about their products, or not taking into consideration the specific needs of rare diseases patients. EURORDIS is particularly cautious of situations that are brought to its attention by its members or other rare diseases patients in Europe.

Should a company's strategy evolve over time and potentially conflict with EURORDIS' positions and need to maintain its independence, financial support from this company would not be accepted or would be discontinued.

Inclusion and exclusion decisions about membership to the EURORDIS Round Table of Companies are made by EURORDIS. Exclusion can be decided by EURORDIS on grounds such as a breach of the EURORDIS Round Table Code of Conduct or of the EURORDIS Policy on Financial Support by Commercial Companies.

3 Types of Financial Support by Commercial Companies to activities promoted by EURORDIS

3.1 Funding of EURORDIS projects

EURORDIS may accept financial or in-kind commercial companies' support for a specific project. It provides EURORDIS with a reliable source of income over a number of years to cover direct costs such as personnel, equipment, consultants or suppliers, mission and travel expenses, as well as related indirect costs (telephone, administrative follow-up of project...).

Companies providing support for a project are publicly acknowledged by EURORDIS (printed documents, website, and electronic communications) to ensure transparency and recognition.

The companies' support has no influence on the design and the conduct of the project, its participants or publication, which will be the property of EURORDIS. Companies supporting a project may be regularly consulted through transparent ad hoc processes such as a donors' committee.

3.2 Funding of EURORDIS events

EURORDIS may accept financial or in-kind contribution by commercial companies for its conferences, workshops, training, capacity-building sessions and other specific events it organises. It provides EURORDIS with a reliable source of income to cover direct costs such as personnel, equipment, consultants or suppliers, mission and travel expenses, as well as related indirect costs.

Funding should come from more than one source.

Companies providing support for an event are publicly acknowledged by EURORDIS (printed documents, website, electronic communications and onsite display) to ensure transparency and recognition.

Sponsors do not exercise any control over the programme, the choice of speakers and the selection of attendees.

3.3 Funding of EURORDIS communication activities

EURORDIS may accept financial or in-kind commercial companies' support for its communication activities, including awareness campaigns and communication tools, such as newsletter, leaflets, reports, and website. It provides EURORDIS with a reliable source of income to cover direct costs such as personnel, equipment, consultants or suppliers, mission and travel expenses, as well as related indirect costs.

Companies providing support will be mentioned in paper and electronic materials. The companies' logo size will be modest to avoid being perceived as an advertisement. Furthermore, the companies' mention is corporate-related and not product-related.

3.4 Membership of the EURORDIS Round Table of Companies

The EURORDIS Round Table of Companies was created to establish a long-term educational relationship between EURORDIS and those companies operating in the health sector that have an interest in orphan drugs, treatments, medical devices, food supplements and health services for people living with rare diseases. This relationship is driven by the principles stated in the Round Table's Code of Conduct, signed by every company becoming a member of the Round Table of Companies.

The specific aims of the EURORDIS Round Table of Companies are:

- To provide EURORDIS with pooled financial support for unrestricted funding with no strings attached, in favour of activities of common interest and benefit, such as:
 - Improving access to information, treatment, care, services and support for people living with rare disease across Europe;
 - Raising public awareness on orphan drugs, rare diseases, and on the need for more research;
 - Empowering rare disease patient groups and improve their advocacy capacity (through information, training and networking);
 - Improving identification and increasing knowledge of rare disease patient groups at the European level; facilitating networking and reaching out to them.
- To educate concerned companies on the common goal of facilitating rapid development and availability of treatments and services for people affected by rare diseases.
- To network with leaders of the rare disease community, patient groups, voluntary health organisations, regulatory agencies and policy makers, and promote open and frank sharing of information, in a neutral forum, on the process, obstacles and incentives for development of treatments.
- To stimulate orphan drug companies to address patient needs and to encourage other companies not yet involved in this field to develop treatments for rare diseases.

- To offer a venue to educate companies on working with patient groups and help them build partnerships with the patient community and academics.
- To facilitate the exchange of views between patient and industry representatives, in order to understand why, when, and how to work with patients.

3.5 One-off charitable donations

One-off charitable donations are not linked to a specific project or activity. They do not create any obligation by EURORDIS to publicly acknowledge the financial support it receives. However, this information may be shared at times such as the EURORDIS Annual Financial Report and Membership Meeting.

3.6 Other In-kind support

Commercial companies may also make non-monetary contributions to EURORDIS, such as:

- Seconded staff or professional services provided without charge
- Equipment donations (e.g. computers and other equipment)
- Meeting rooms
- Other non-monetary contributions (e.g. furniture, printing services)

4 EURORDIS involvement in activities of the health industry

This section deals with EURORDIS involvement in activities related to medicinal products, medical devices or services which are marketed or distributed by industry or still under development. This new additional section in the 4th revision of the 'EURORDIS Policy on Financial Support from Commercial Companies' derives from the 'Code of Practice between Patient Organisations and the Healthcare Industry' developed in 2008-2009 by a group of patient organisations including EURORDIS.

4.1 Promotional activities related to approved prescription medicines

All promotional activities related to approved medicines are not permitted within the current EU legislation and industry codes of ethics. EURORDIS does not get involved in activities that can be possibly associated with a promotional strategy. EURORDIS always keeps in mind potential conflicts of interest and is guided by its own agenda, lead by the interests of rare diseases patients.

Types of activities that can be considered promotional under European and national legislation:

- Disseminating unbalanced, non-validated or partial information on products, services or MDs distributed or marketed by a company;
- Being quoted in the company's communication in favour – or against – a product;
- Participating as a speaker/attendee in a company's product launch event ;
- Participating in an ad hoc meeting sponsored by an individual company to inform patients on their products;
- Agreeing that a company displays or disseminates a patient organisation's own material on the company's exhibition stand at any trade exhibition or scientific conference;
- Appearing in promotional materials for a certain product or to testify as a "consumer" of that medicine. Contact information to patient organisations can be included in a separate section.

4.2 Industry press releases

- EURORDIS refuses to be quoted in industry press releases that relate to a marketed product or a product under development;
- If EURORDIS feels the need to communicate to media about a product, it will issue its own press release, independently of industry;
- If a company quotes EURORDIS' opinion or refers to EURORDIS' own communication materials without EURORDIS' permission, EURORDIS will object to the company by registered letter (copy to the national industry association of the company).

4.3 Training organised by industry or a group of companies

EURORDIS is aware that not all themes for a potential training provided by a commercial sponsor are neutral, either about general themes or on more product related themes. Some programmes may have an influence on EURORDIS representatives' way of thinking.

In this context, it is important that the programme is sponsored by several companies, rather than a single one, and that EURORDIS' representatives have been involved in the preparatory phase of the training programme.

Generally speaking, it is preferable to find an equivalent programme run by a Patient Group and advisable to ask commercial companies to sponsor EURORDIS participation in the training.

4.4 Participation in conferences or seminars held by industry

- If EURORDIS representatives participate in an industry launch or promotion of a product, no photo must be taken or released without prior authorisation of the person involved. To this end, arrangements in writing prior to the event are recommended.
- EURORDIS representatives will insist that multiple sources of information are involved in an ad hoc meeting sponsored by a single company, aimed at informing patients about their products. Information meetings without the presence of independent experts could be considered as an infringement of the Pharmaceutical Advertising Directive.

4.5 Individual compensation

There are several situations where industry may propose honoraria to EURORDIS representatives:

- Participation in meetings or Conferences organised by the company;
- Participation in meetings or Conferences organised by a third party;
- Reviewing industry materials, leaflets, protocols, etc.
- Consultancy on industry policy, advisory committees and Boards, etc.

EURORDIS representatives are as much entitled as healthcare professionals to receive honoraria for similar circumstances/services?

Nevertheless, EURORDIS internal policies and agreements guarantee full transparency:.

- For volunteers: Before receiving any individual compensation, all EURORDIS volunteers will ask clearance approval to the CEO and who will inform the Board of Officers of his decisions.
- For staff: All EURORDIS staff members may not directly receive individual compensation, this compensation will be received by EURORDIS, after the CEO's explicit clearance approval.

4.6 Involvement in industry-source websites or other material

EURORDIS does not contribute to industry websites.

4.7 Diseases awareness campaigns by industry

Disease awareness campaigns can be considered as an indirect form of advertising in some Member States. It is unwise that EURORDIS be associated unless these campaigns have the backing of the public health authority. EURORDIS must ensure that any campaign its representatives participate to is not only an industry initiative but does respond to a well characterised public health need. Any product information disseminated by the industry during these campaigns must be based on the Summary of Products Characteristics (SmPC).

Companies wishing to mention the name of EURORDIS must ask prior written permission.

5 Process

5.1 Documentation

When approaching or being approached by a commercial company, EURORDIS usually requests information such as the main business activities of the company. EURORDIS also does background research such as the company's reputation with concerned patient groups and regulators.

EURORDIS provides companies with its activity and financial reports, and its Policy on Financial Support by Commercial Companies. EURORDIS requests every commercial company it collaborates with to carefully read and approve this Policy. A copy of this Policy remains with the company.

5.2 Accountability

Commercial companies supporting EURORDIS receive the annual activity report and the annual financial report covering the period of the donation, after these documents have been approved at the Annual Membership Meeting.

The company receives interim and final reports concerning the project. When financial support is provided in the context of a special initiative, the company receives a copy of relevant documents.

5.3 Recognition and visibility of the relationship

Companies may wish to be publicly acknowledged for their financial support. Prior agreement will be reached on communication matters and detailed in the contract. As part of its transparency policy and for 'fair' partnership reasons, EURORDIS may provide adequate recognition to a commercial company for its financial support and commitment.

The level of visibility given to the company, including the logotype used and the wording in the communication material, require prior agreement from both parties.

When a commercial company does mention the financial support it gives to EURORDIS, the wording used and/or EURORDIS' name and logotype cannot be used without prior approval by EURORDIS. Any public information should be jointly agreed between the President or the Chief Executive Officer of EURORDIS and the commercial company.

5.4 Transparency policy

By adopting and publishing a transparency policy on relationships with commercial companies, EURORDIS acknowledges that the financial support it receives will never compromise its independence and future policy decisions.

The Annual Financial Report of EURORDIS reflects the level of financial support it receives from corporate donators and provides fair and reliable information to members and the public. The Annual Financial Report is published on the EURORDIS website.

Financial support is acknowledged in projects and initiatives' reports and documents, as well as in public presentations, other relevant documents, and on EURORDIS' website. The EURORDIS website has a section where financial information is provided; it includes a list of all donors to EURORDIS.

5.5 Derogation

In case of *force majeure* or situation not foreseen in this EURORDIS' Policy on financial support by commercial companies, a derogation is possible. Any derogation to this policy, and in particular to the transparency rules applied for commercial companies in the health sector, has to be officially and transparently discussed, duly motivated, and adopted by the Board of EURORDIS. If such decision was to be significant, it would be mentioned in the Annual Report and the members would be informed through the reports at the Annual General Assembly.

6 Final remarks

The scope of this EURORDIS Policy is its relationships with commercial companies and responds to the need felt by EURORDIS to establish clear rules on financial support it may receive from commercial companies, in particular from commercial companies in the health sector.

While being a EURORDIS Policy Paper, any other patient organisation, whether a member of EURORDIS or not, may feel inspired and encouraged by this Policy when elaborating its own rules in this field.

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

Association: EURORDIS

Registered office: Paris

Siret no.: 41345906600028

INTERNAL REGULATIONS

CONTENTS

	PAGE NO.
1 PREAMBLE	2
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
2 ETHOS AND WORKING CONDITIONS	3
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
3 SALARY AND BENEFITS	8
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
4 EMPLOYEE RIGHT OF EXPRESSION	9
4-1 The role of staff delegates (COMPULSORY)	9
4-2 Direct and collective right of expression	9
5 PENALTIES AND RIGHT OF DEFENCE (COMPULSORY)	10
5-1 Scope	10
5-2 Scale of penalties	10
5-3 Disciplinary procedure	10
6 HEALTH AND SAFETY (COMPULSORY)	10
6-1 Health and hygiene	10
6-2 Prevention and safety	10
7 ENTRY INTO FORCE AND AMENDMENTS (COMPULSORY)	11
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. 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

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

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

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

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

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

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

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

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

❖ ARTICLE 5 PENALTIES AND RIGHT OF DEFENCE (COMPULSORY)

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.

❖ ARTICLE 6 HEALTH AND SAFETY (COMPULSORY)

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

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.

❖ ARTICLE 7 ENTRY INTO FORCE AND AMENDMENTS (COMPULSORY)

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

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

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

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



EURORDIS
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
- ▶ Be a privileged Rare Disease Day participant (last day of February each year, 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

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 of Directors Members Role and Responsibilities

The Terms of Reference of the Board of Directors are providing the roles and responsibilities of the Board of Directors.

Rules & Commitment

- Directors act in the scope of and in accordance with EURORDIS' Statutes and By-Laws and report to the General Assembly.
- 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.
- 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, who is elected on the Board of EURORDIS, not the member organisation.
- 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.

Role & Responsibilities

Strategic Planning

- Participate in creating and reviewing strategic orientations.
- Review and approve, on an annual basis, the annual work plan (action plan, budget, team chart, governance chart), review annual activity and financial reports.
- Act as a collegiate body with collective responsibility.

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

- To contribute specific skills, interests and contacts to the development of EURORDIS and its aims.

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 of overseeing the admission or the expulsion of members (approved by the BoO) according to EURORDIS statutes

Person Specification (for both BoD and BoO Members)

Essential

- Living with or having personal knowledge of rare disease.
- 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)

- 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 and Deputy 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. The Deputy General Secretary operates as alternate whenever necessary and most relevant.

Governance Management of the Organisation

The General Secretary is responsible for these tasks. The Deputy General Secretary works closely with the General Secretary on these tasks, providing another analysis. They work closely with the Governance Senior Manager.

- 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, the Chief Executive Officer and the Governance Senior Manager, 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.
- 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.
- Conduct regular assessment of the EURORDIS By-laws and propose revisions as necessary.

Membership

- Together with the Senior Manager of relations with Patient Organisations and the Governance Senior Manager, ensure that the membership applications are evaluated against the EURORDIS Membership criteria, and provide a recommendation for the Board decision on the membership application.
- Together with the Chief Executive Officer, handle situations of tension with National Alliances, European Federations and other members, providing moderation when necessary.
- Act as a spokesperson within the network of Members, particularly the National Alliances and European Federations

Commitments

- Allocate enough time for the Governance (Minutes, TAD, Activity Report, By-laws) and Membership (applications, conflict management, travel as spokesperson) duties



EURORDIS President and Vice-Presidents Role and Responsibilities

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

The Vice-Presidents are responsible to assist the President in all these main duties and to ensure the role as necessary in the absence of the President and/or in order to ensure representation of EURORDIS externally. The Vice-Presidents, depending on their skills and profiles, are also advising on strategic policies and programmes.

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 Core Leadership Team
- 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:

- 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.

2 Fulfilment of governance responsibilities:

- Propose the draft agenda, of both Board of Directors and of Officers meetings, as well as General Assemblies.
- Chair meetings both of the Board of Directors and of Officers, as well as General 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 Chief Financial Officer, Chief Executive Officer 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 CEO or the Board of Officers.
- 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 Core Leadership Team:

- 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
- Set, with the Board, an annual calendar of Board meetings and major EURORDIS events.

4 Represent and speak on behalf of Eurordis

- Serve as 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 the two Vice-Presidents are asked to give a reasonable 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 financial operations are 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, the Chief Financial Officer and Core Leadership Team, 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 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 with the Chief Executive Officer, the Chief Financial Officer and auditors, that annual financial and audits 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

- Allocate enough time to ensure the financial duties
- Ensure regular liaison with the Chief Executive Officer and the Chief Financial Officer

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)



Terms of Reference

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, 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.

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.

Eligibility Criteria for European Federations

To join the Network of European Federations, the organisation must:

- Be a full or associate member of EURORDIS
- Federate national patient organisations for a specific rare disease/group of diseases from at least 3 European countries

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.
- (f) Collaborate with European Reference Networks (ERN) and participate European Patient Advocacy Groups (ePAGS)

Organisation:

The **Network of European Rare Diseases Federations** will gather European/international 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, including a one-day training**. Workshops will take place in different countries over time.

A dedicated **Web Section** is available on eurordis.org with all relevant information on the European Network, including the list of members. A CEF Facebook group is open to all CEF members.

General financial guidelines

EURORDIS will cover the cost of the yearly 2-day 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, equipment, coffee-break, lunch. EURORDIS will explore all possibilities to help cover expenses for federations which cannot afford participation, based on fellowships covering all or part of expenses.

Support to European Federations

Members of the Network of European Federations can apply for the yearly call "Support to European Federations", which aims at supporting the federations with their network meetings. (see Terms of References "Support to European Federations")

ePAG Constitution

EURORDIS approach to structure patient partnership in the European Reference Networks

(31 Aug 2022)

Contents

1. Terms and Definitions	2
2. Introduction	4
3. Framework to structure patient partnership in the ERNs.....	5
4. Mandate for patient partnership in the ERNs	6
5. EURORDIS role to support patient partnership in the ERNs	6
6. EURORDIS ERN & ePAG Team.....	6
7. EURORDIS ePAG transversal working groups	7
8. Conflict Mediation.....	8
9. Amendment of ePAG Constitution.....	9
Annex I: Mediation Process	10
Annex II: Request for Mediation Form	11

1. Terms and Definitions

European Reference Network (ERN): a group of highly specialised healthcare providers that have been awarded with the membership of a given Network. Networks focus on rare or low prevalence and complex disease(s), condition(s) or highly specialised intervention(s) as regulated by article 12 of the Directive 2011/24/EU on patients' rights in cross-border healthcare¹.

Board of Member States (BoMs): a governing body consisting of representatives from Member States across EU Member States and European Economic Area responsible for the formal designation of European Reference Networks as provided in the Commission Implementing Decision 2014/287/EU². The Board of Member States (BoMS) has the responsibility of approving European Reference Networks (ERNs).

Patient Organisations (PO): Non-profit organisations that are legally registered and operating in [Europe](#) (48 countries as defined by EURORDIS based on definitions by the EU, the Council of Europe and the WHO-Europe), representing patients and families living with a rare disease, has a governing board made up of a majority patients or of family members of patients, is financially independent, particularly from the pharmaceutical industry (max. 50% of funding from several companies) and has proven activities such as patient support and/or advocacy activities and/or research. Individual ERNs may waive some of these requirements in exceptional cases, due to the particularity of patient-driven organisations and of rare diseases, as well as for historical or contextual reasons.

Patient partnership: a mutual relationship between persons living with a rare disease and other stakeholders where input from people living with a rare disease or caring for someone with a rare disease routinely and formally informs policy reflections and decisions. Patient partnership implies going beyond empowerment and engagement but considering people living with a rare disease and their advocates as equal partners and actors in policy and programme design and evaluation. For the purposes of this governance framework the terms "patient involvement" and "patient partnership" are used interchangeably.

ERNs Associate Partner - Patient Organisation: Patient Organisation registered and operating in [Europe](#) that has been invited to partner with an ERN, complies with the requirements established by the ERN and has gone through the Network's application process to designate a patient representative to be involved in the ERN activities as an ePAG advocate. An Associate Partner agreement is signed between the ERN and the Patient Organisation to establish the terms of this collaboration.

ERN Supporting Partner - Patients: Patient Organisation with a national, European or international remit with no designated patient representative in the ERN, individual patients and family members or social-media patient support groups that have been invited to collaborate with an ERN. A Supporting

¹ OJ L 88, 4.4.2011, p. 45, Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare

² OJ L 174, 17.5.2014, p. 79, Commission Implementing Decision 2014/287/EU of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks

Partner Agreement is signed between the ERN and the Patient Organisation, individual or support group to establish the terms of this collaboration.

ePAG Advocate: A patient representative to a specific European Reference Network who has been endorsed by an ERN Associate Partner-Patient Organisation to be active in the ERN governance structure including its working groups. For the purpose of this framework, the terms ePAG advocate, patient representative and patient advocate are used interchangeably.

European Patient Advocacy Group (ePAG): A patient group, specific to each European Reference Network, composed by patient advocates that have been endorsed by a Patient Organisation established by EURORDIS to optimise patient involvement in the ERNs' decisions and activities. Some ERNs have formally recognised these groups as part of their governance structure. The overarching objective of the ePAG is to ensure that the needs of people living with rare and complex conditions covered by the ERN are included in its strategic and operational delivery.

ePAG Steering Committee: Transversal working set up and managed by EURORDIS composed by ePAG Advocates from the 24 ePAGs sitting in the ERNs Boards or Executive Committees to provide strategic advice, share experience and knowledge from the 24 ERNs.

ePAG Transversal Topic Based Groups: Transversal peer learning working groups set up and managed by EURORDIS composed by ePAG Advocates dedicated to a specific topic, e.g.: clinical practice guidelines and clinical decision support tools, communication and dissemination, research and registries, training and education, monitoring and evaluation.

ERN Coordinator: the person appointed as the Coordinator of the Network by the Member of a European Reference Network chosen as the coordinating Member as referred to in recital 3 and Article 4 of Delegated Decision 2014/286/EU.

ERN Project Managers: the persons in charge of coordinating the Networks' collaborative activities, financial and technical reporting, monitoring and evaluation.

Board of the ERN: the coordination body for each Network responsible for its governance, as foreseen in the Commission Delegated Decision 2014/286/EU³ (Annex I)³. All members of the Network must be represented on the Board.

ERN Core Networks (or sub-thematic networks): ERNs are thematic networks covering a number of rare or complex diseases and/or highly specialised interventions or surgery, as defined in their ERN application scope. Each ERN is structured differently to reflect the needs and grouping of their rare diseases into a number of 'Core Networks', also known as Disease Specific Networks or Sub-Thematic Working Groups, (e.g.: ERN-Lung has 9 core networks including Cystic Fibrosis, Pulmonary Hypertension, etc). Each one of these networks have a clinical committee or board of experts in that specific field to coordinate and lead the ERN activities specific to this disease area.

ERNs Coordinators Group: a working group that brings together the Coordinators of the 24 ERNs to discuss common technical matters.

³ OJ L 174, 17.5.2014, p. 71, Commission Delegated Decision 2014/286/EU of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil

ERN Transversal Working Groups: Transversal working groups set up by the ERN Coordinators, sometimes jointly with the ERNs BoMs, to discuss on topics and activities that are cross-cutting all 24 ERNs e.g.: clinical practice guidelines and clinical decision support tools, legal and ethics, research, training and education, integration of ERNs into national health systems, monitoring and evaluation.

ERN Healthcare Provider (HCP) Member: a centre of medical expertise / excellence or specialist team treating rare and complex diseases, who has been endorsed by their Member State as an expert centre, is in compliance with the criteria and conditions laid down in Article 5 of the Commission Delegated Decision (2014/286/EU) and has been awarded with the membership of a given network.

ERN Affiliated Partner: Member States with no Member of a given Network may decide to designate healthcare providers with a special link to a given ERN, following a transparent and explicit procedure. Those providers might be designated as Associated National Centres focusing on the provision of healthcare, Collaborative National Centres focusing in the production of knowledge and tools to improve the quality of care or a National Coordination Hub who connects their national healthcare system with ERNs, coordinating information and referrals.

ERN Supporting Partner: healthcare providers, medical societies, and any other entity or individual experts which, without having a commercial relation with the ERNs and their Full Members or Affiliated Partners, or with the European Commission, contribute in different ways to the work of the networks.

EUCERD: European Union Committee of Experts on Rare Diseases established to support EU policy on rare diseases, and specifically provide policy guidance on the effective implementation of the 2008 EU Commission Communication on Rare Diseases and the 2009 Council (of the European Union) Recommendation on action in the field of rare diseases. In 2013 it was replaced by the European Commission Expert Group on Rare Diseases (CEG –RED) whose mandate terminated in 2016. The EUCERD and CEG-RD brought together representatives from: the 28 EU Member States, Iceland, Norway, Switzerland, the EU Commission, the Committee for Orphan Medicinal Products of the EMA, industry, academia, eight individual experts as well as eight patient advocates.

2. Introduction

European Reference Networks (ERNs) have been established on the founding principle of patient empowerment and involvement⁴, to improve access, safety and quality of diagnosis, care and treatment for people living with a rare or complex condition, or who require highly specialist interventions that call for the centralisation of cases, expertise and resources⁵. Rare disease patient representatives are experts by experience and their participation in the ERNs is central to represent patients' needs and perspectives in the Networks' discussions and activities, and ultimately to support ERN delivery on their goals.

⁴ OJ L 174, 17.5.2014, p. 71, Commission Delegated Decision 2014/286/EU of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil, Annex 1(2b)

⁵ OJ L 174, 17.5.2014, p. 71, Commission Delegated Decision 2014/286/EU of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil

The European Union Committee of Experts on Rare Diseases (EUCERD) ERN Recommendations and Addendum⁶, formally recognise the critical and integral role that patient representatives play as formal members of the decision and opinion making structures of the ERNs. As experts by experience, rare disease patients draw on their knowledge of living with a rare disease, enhancing the expertise in clinical services and research networks, and building a critical mass of knowledge to tackle the EU rare disease public health priority.

EURORDIS and the rare disease patient community have worked together for over a decade to develop the concept of European Reference Networks as patient centred networks, rooting patient involvement at all levels and across all ERNs and building on the experience and recognition gained from the pilot ERNs that recognised and valued patient representatives' contribution in rare disease networks.

In 2016, EURORDIS in collaboration with the European rare disease community established 24 European Patient Advocacy Groups (ePAGs) as forums to optimise the involvement of patient representatives in the strategic and operational delivery of the 24 ERNs. Each ePAG corresponds to the scope of one of the 24 individual ERNs, aligning patient organisations and clinicians, experts and researchers working on the same rare or complex disease or highly specialised intervention. These groups are composed by appointed patient representatives, some of which were elected in 2016 and others who have been co-opted.

ePAGs, bring together over 300 patient representatives who are actively involved in the ERNs. ePAG advocates play a fundamental role to connect the Networks with the wider rare disease patient community and, where relevant, to champion the diversity of views of these wider patient community relevant for each ERN, and not just of their own disease area.

3. Framework to structure patient partnership in the ERNs

This document describes EURORDIS role to support patient partnership in the ERNs. In addition, in collaboration with patient representatives and ERN project managers EURORDIS has developed four governance templates to structure patient partnership in the ERNs that individual ERNs may adapt to their own specificities:

1. [Sections on rules for patient engagement to be included in the ERN bylaws;](#)
2. [Rules for Associate Partners Representatives \(ePAG advocates\);](#)
3. [Associate Partners agreement between the ERN and Patient Organisations that have designated an ePAG advocate;](#)
4. [Supporting Partners agreement between the ERN and individual patients and family members and patient organisations with no designated ePAG advocate in the ERN.](#)

These four templates, together with the present document, constitute EURORDIS framework to structure patient partnership in the ERNs. A framework that recognises the heterogeneous nature of the rare disease patient community and their diverse needs while ensuring unity, solidarity and equity of patient representation from the rare disease community.

⁶ European Union Committee of Experts for Rare Diseases Addendum: Rare Disease European Reference Networks (2015)

4. Mandate for patient partnership in the ERNs

According to the EU Committee of Experts on Rare Diseases (EUCERD)⁷, patients and patient representatives should play an active role in the decision and opinion making process of the ERNs and be involved in structural and clinical network activities. The Expert Group recommended that ERNs demonstrate meaningful patient involvement, patient-centredness and empowerment through recognition of the role of patients as experts by experience and co-producers of knowledge in the ERNs structural and clinical activities.

5. EURORDIS role to support patient partnership in the ERNs

EURORDIS supports and provides patient representatives involved in the ERNs with the information, knowledge and skills that they need to engage and partner effectively with clinicians in the Networks' collaborative activities, specifically by:

- Creating working groups with ePAG advocates from different ERNs on relevant topics to disseminate information and share knowledge (e.g.: research and registries, clinical practice guidelines, education and training, evaluation and monitoring, etc.);
- Creating opportunities for peer-to-peer learning and developing capacity building activities;
- Developing practical guides to facilitate patient partnership in different ERN-related activities;
- Facilitating team building and partnership approach in the ERNs between patient representatives and clinicians;
- Engaging with patient representatives, clinicians and ERN project managers to assess the value of patient partnership in the ERNs;
- Engaging with the ERN project managers to implement a harmonised approach to patient partnership in the ERNs;
- Supporting the recruitment of new ePAG advocates;
- Facilitating the collaboration between ePAGs, National Alliances and European Federations on ERN matters;
- Mediating in conflicts.

6. EURORDIS ERN & ePAG Team

EURORDIS ERN & ePAG team supports all patient representatives who are active in the ERNs. The team is composed by EURORDIS ERN & Healthcare Director, 1 Senior Patient Engagement Manager, 1 Junior Patient Engagement Manager, 1 part-time Senior Patient Engagement Manager and 1 part-time Senior

⁷ European Union Committee of Experts for Rare Diseases Addendum: Rare Disease European Reference Networks (2015)

ERN and Healthcare Advisor. In addition, this core team is supported by EURORDIS leads in Public Affairs, Research, Therapeutic Development & Access and EURORDIS Communications Team.

7. EURORDIS ePAG transversal working groups

EURORDIS has moved progressively from providing hands-on support to individual ePAG groups to supporting patient representatives via cross-ePAG groups working groups (WGs) focusing on transversal topic areas. Currently EURORDIS manages the following ePAG WGs:

1. ePAG Steering Committee
2. Connecting Patients with ERNs Working Group
3. ePAG Clinical Practice Guidelines Working Group
4. ePAG Research and Registries Working Group
5. ePAG Training and Education Working Group
6. ePAG AMEQUIS Task Force
7. ePAG Patient Partnership Working Group

All of the above working groups are open on an ongoing basis to all ePAG advocates. The exception is the ePAG Steering Committee which is only open to 2 advocates per ePAG, who sit on the ERNs Boards or Executive Committees. In each individual ePAG, patient representatives discuss how to distribute the work and who will participate to the different EURORDIS ePAG WGs based on their interests and availability.

5.1 ePAG Steering Committee

EURORDIS has set up an ePAG Steering Committee which is a transversal committee of ePAG advocates from each of the 24 ePAGs.

The ePAG Steering committee is composed by ePAG advocates of the 24 ERNs who sit on the ERNs Boards or Executive Committees and EURORDIS.

This group provides advice to the ERNs, the European Commission (EC) and the ERN Board of Member States (BoMs) on patient partnership and ensures a common approach to involving patients in the ERNs. It does this by:

- identifying, sharing experiences, discussing and making recommendations regarding issues which are common to all or a sub-set of ePAGs.
- reporting on important updates on ERNs-related initiatives to the 24 ePAGs and gathering their feedback.
- identifying areas for additional horizontal ePAG working groups.

ePAG Advocates who are members of the ePAG Steering Committee, may choose to become EURORDIS Volunteers and have an official permanent mandate to represent EURORDIS. As EURORDIS Volunteers they will have to adhere to the principles and obligations described in the [EURORDIS Charter of Volunteers](#) and report each year the time spent working for EURORDIS. Conversely, EURORDIS staff provide necessary support to help volunteers fulfil their mission. The monetary value corresponding to the time spent by EURORDIS volunteers will be taken into account in EURORDIS

accounts as an in-kind contribution. To formalise their designation, ePAG advocates will have to send an email to EURORDIS ERN team expressing their interest to become a EURORDIS Volunteer.

5.2 ePAG transversal topic-based working groups

Through this working group structure, EURORDIS and the patient representatives involved in the ERNs share information and updates, learn from each other, develop materials and support ePAG advocates to engage on important topics. EURORDIS has set up and manages the following transversal working groups:

1. **Connecting Patients with ERNs WG:** facilitates collaboration with Rare Diseases National Alliances to produce communication resources to reach out to patients. to facilitate collaboration between ePAG advocates and Rare Diseases National Alliances, so that the information on ERNs is more easily shared at national level.
2. **ePAG Clinical Practice Guidelines WG:** supports patient partnership in the development and implementation of clinical practice guidelines (CPG) and other clinical decision support tools (CDST).
3. **ePAG Research and Registries WG:** supports patient partnership in research activities.
4. **ePAG Training and Education WG:** develops training & capacity building materials and activities to address ePAG advocates training needs.
5. **ePAG AMEQUIS Task Force:** supports patient partnership in the monitoring, evaluation and quality improvement system of the ERNs.
6. **ePAG Patient Partnership WG:** supports implementation of tools and processes to foster a patient-clinician partnership culture that is similar across all ERNs.

8. Conflict Mediation

If a dispute arises between ePAG advocates, they commit in good faith to try to take steps to resolve the dispute together. They may seek advice from EURORDIS if needed by approaching any member of the EURORDIS ERN team.

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

Once the agreement to mediate has been obtained from all parties involved, the mediation process will be conducted following the process described in Annex I. The parties commit to adhere to the terms of the mediation agreement that may result from a mediation process that they voluntarily decide to initiate.

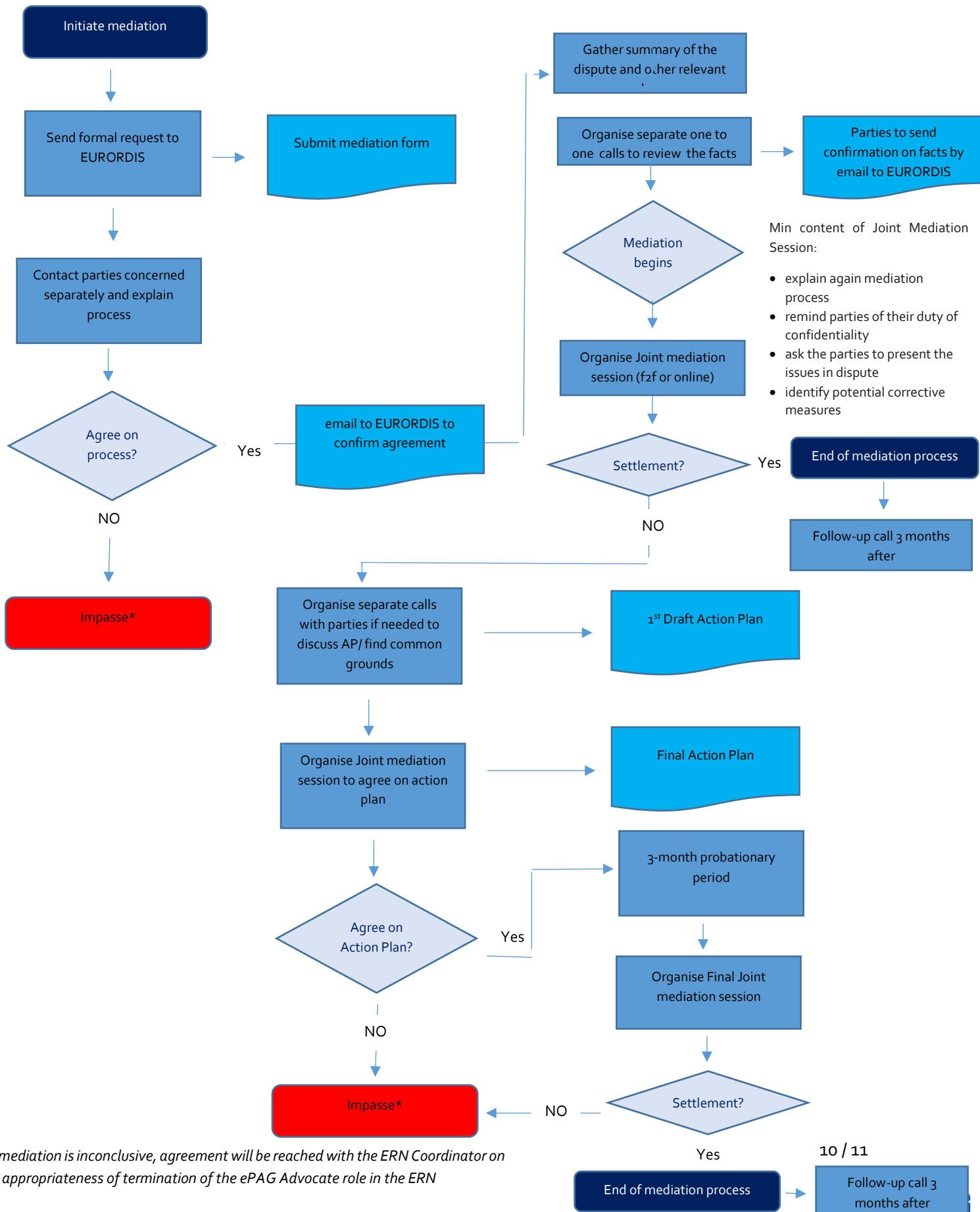
Confidentiality will be guaranteed in any mediation activity in which EURORDIS is requested to engage, however the ERN Coordinator will be informed on a confidential basis in all cases. If mediation is inconclusive and the circumstances are untenable, agreement will be reached with the ERN Coordinator on the appropriateness of termination of the ePAG advocate mandate in the ERN.

In disputes involving clinicians and patients, an ERN Coordinator and the ePAG Chair can jointly ask EURORDIS to mediate if the dispute cannot be settled within the ERN. The same process described in Annex II will be used to mediate in these conflicts.

9. Amendment of ePAG Constitution

The ePAG Constitution will be reviewed by the ePAG Steering Committee on an annual basis to ensure it remains fit for purpose and will be adopted by the EURORDIS Board of Directors.

Annex I: Mediation Process



Annex II: Request for Mediation Form

Having your dispute mediated by EURORDIS is a voluntary process. When EURORDIS receives your Request for Mediation form, a member of the EURORDIS ERN team will contact the other parties and seek their agreement to mediate. You will receive copies of our communications to the other parties.

Once all parties have agreed to the process and mediation is initiated, the parties commit to adhere to the terms of the mediation agreement that may result.

Please fill out the form completely. **Missing information may delay the processing of your request.**

Party seeking mediation:

Name

Surname

Email address

Telephone

Please provide a brief description of the dispute. Include a summary of what occurred, relevant dates, names and titles of all individuals involved, and the settlement requested (e.g. resignation of a Chair, selection of new ePAG Advocate or what type of solution you are seeking for).

Please provide the following information for all parties to the dispute:

Name

Email address

Telephone number

Please email this completed form to: ines.hernando@eurordis.org

Roles and responsibilities of the Therapeutic Action Group (TAG) (adopted in November 2022)

The following description clarifies the roles and responsibilities of the Therapeutic Action Group (TAG) members as EURORDIS volunteers and patient representatives (members and alternates) within the European Medicines Agency's Committees.

General role:

In addition to the general work performed by each Committee member/alternate, the TAG patient representative (in collaboration and with the support of EURORDIS) is expected to:

Role:

- Represent the interests of persons living with a rare disease and provide the patients' perspective (as patient, carer or advocate) on behalf of those directly affected by regulatory decisions.
- Become a EURORDIS volunteer: i.e., being publicly identified as such (e.g., appearing onto the website, etc.), acting as an official speaking person on behalf of EURORDIS and while maintaining visible their affiliation within their own organization. Being a EURORDIS volunteer enhances visibility and help to maximize the advocacy messages of the volunteer's respective patient organization.
- As such become part of the EURORDIS advocacy committee (ADVOC) which brings together EURORDIS Board of Directors, key volunteers with permanent mandate and key staff members.

Scope of the work:

- To prepare for and participate in relevant EMA meetings.
- Participating actively in the EURORDIS Therapeutic Action Group monthly conference call and other relevant EURORDIS meetings. This includes liaising with EURORDIS TAG coordinator on a monthly basis by providing feedback from the Committee meetings.
- On occasion, provide evidence to support EURORDIS Advocacy work, including EURORDIS input into consultations and contributions to policy and guidelines across rare diseases. This will also support your work at the EMA and withing your community.
- Being closely involved in EURORDIS activities related to therapeutic development.
-

Time Commitment / Workload

- Time in the Committee meetings at the EMA:
 - 3-4 days/month in Amsterdam/remotely depending on the EMA schedules and organization.
 - additional meetings in Amsterdam or elsewhere may be organized (e.g., Strategic and Review learning meetings held in the context of the EU Presidency).
 - Reimbursement for travel, accommodation and allowances according to the EMA rules.

- Homework: we estimate about 4-5 days/month of work to prepare and follow-up the meetings. 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.
- Regular report on the time spent/commitment as EURORDIS volunteer (at least on an annual basis)

Capacity-building opportunities: approximately 3-8 days/year upon your 'availability/willingness' and according to your expertise/interest in the topics

- Speaking/Participating in the annual EURORDIS Membership Meeting, the European Conference on Rare Diseases and occasionally the EURORDIS Round Table of Companies Workshops. Expenses covered by EURORDIS.
- Speaking/Participating in national meetings (e.g., national rare disease alliances) or international meetings (e.g., DIA, WODC and other forums). Expenses covered by EURORDIS to be discussed on a case-by-case basis.

Confidentiality, Requirements and Conflicts of Interest

- All patients' representatives are expected to comply with the EMA rules, i.e., policy on confidentiality and declaration of potential conflict of interest.
- Patients' representatives must declare their potential Conflicts of Interests at three levels.
 - i) those of EURORDIS (provided by EURORDIS twice a year) if they are staff of EURORDIS or for transparency purposes
 - ii) those of their own patient organization provided by their organization if they are staff or for transparency purposes and
 - iii) their own personal Conflicts of Interests as individuals in all cases.

All Declarations of Conflict of Interest should be submitted to EMA. Please be advised that once you have submitted and signed the form, the Agency will publish your declaration of interests on its website.

By signing this document, you agree to the above-mentioned and with the [EURORDIS charter of volunteers \(read here\)](#).

Name, date and signature



Social Policy Action Group

Terms of Reference

Adopted in November 2023

Introduction

Most people who live with a rare disease face serious everyday challenges and many societal barriers, while also living with visible or invisible disabilities. The barriers they face include the lack of holistic, integrated and lifelong care and support, as well as limited access to social and disability rights, limited participation in education and employment, and reduced income.

Such barriers prevent people living with a rare disease and their families, often the main carers, from living more independently and from fully participating in various areas of society, while also exposing them to a high level of psychological, social, and economic vulnerability.

Purpose

EURORDIS' ambition is to see people with a rare disease and their families integrated in a society that:

- Is aware of their needs and effectively provides timely, high-quality care according to those needs.
- Breaks down barriers in access to care, treatment, education, employment, leisure, psychological support and all aspects of participation in society.
- Enables them to fully enjoy their fundamental human rights, on equal footing with others.

EURORDIS' work to advance this ambition includes:

- Advocating for integrated health and social care, with a lifelong and holistic approach.
- Advocating for non-discrimination and access to social and human rights, i.e., social protection, social and community services, independent living support, education and employment.
- Advocating for the adequate assessment and recognition of the disabilities faced by people living with a rare disease, as well as to improve their access to disability related rights.
- Engaging with EU institutions and partnering with external experts and organisations, to provide input to the design of relevant policies, initiatives and funding instruments.
- Empowering its members and the rare disease community on social and other human rights topics.
- Contributing to the design, implementation, and promotion of relevant good practices.
- Developing or taking part in relevant European projects.
- Contributing to or leading publications on relevant topics.

Mission

The EURORDIS Social Policy Action Group (SPAG) will support EURORDIS' work to shape policies and practices that improve the access of people living with a rare disease and their families to holistic care, social and human rights. The activities of the SPAG will be regularly defined, in line with EURORDIS' mission, strategy and priorities.

Objectives

The mission of the SPAG focuses on the following objectives:

- Informing on and raising awareness of the everyday needs and barriers faced by people living with rare diseases, including rare cancers, and their families.
- Advising EURORDIS to ensure the formulation of person-centric approaches to the different issues related to holistic care, social and human rights.
- Advocating for policies and services that address the unmet needs and societal barriers, at European, national and regional levels; pursuing opportunities to support EURORDIS with influencing high-level decision making.
- Facilitating the participation of people living with a rare disease and their families in relevant consultations by sharing and collecting contributions from individuals and their organisations.
- Enabling EURORDIS to bring the voice of people living with a rare disease and their families to specific projects and initiatives.
- Empowering their organisations and the rare disease community to advocate for holistic care, and for the social and human rights of people living with a rare disease and their families.

Composition

The SPAG is composed of 15 to 20 members, representing a diversity of European countries, rare diseases, disabilities, ages, and backgrounds.

The SPAG members are:

- Individuals living with a rare disease, family members or other representatives of an organisation representing people living with rare diseases.
- Other experts with experience in social policy, social services, education, employment, disability, independent living, integrated care or other relevant fields.

Mandate

The members of the SPAG are nominated for a term of 3 years, from November 2023 to October 2026.

Following a review of the achievements and continued need for the SPAG, EURORDIS' Board of Directors could approve a renewal of the SPAG.

There have been two previous SPAG mandates, from 2015 to 2022, with distinct members and objectives¹.

¹ In its first mandate (2015-2018), the SPAG was designated as Social Policy Advisory Group and composed of 10 representatives. It was then renamed to Social Policy Action Group, for its second mandate (2019-2022), when it was composed of 9 representatives. The work of the SPAG directly supported several important milestones for the rare disease community, many of which are listed in the "useful resources" section of these Terms of Reference (page 4).

Status and Code of Conduct

The SPAG is an informal network hosted by EURORDIS. Membership is voluntary.

SPAG members are EURORDIS volunteers who must adhere to these Terms of Reference and to the [EURORDIS Charter of Volunteers](#).

The responsibilities of the SPAG include a commitment to participate actively in the work of the group. SPAG members are responsible for liaising with their organisation, and for informing their organisation about the activities of the SPAG and their own membership.

Confidentiality and Potential Conflict of Interest

Members are expected to respect the confidentiality of meetings. When there is a potential conflict of interest, members are expected to notify the EURORDIS staff member responsible for coordinating and supporting the SPAG and to exclude themselves from the specific agenda items for which there is a potential conflict of interest.

Meetings

The SPAG will meet a 3 times per year. The meetings will serve as a platform for knowledge sharing among participants and to discuss key issues.

Additional workshop sessions may take place to allow for focussed debate on key issues.

Meetings will primarily be virtual, to facilitate participation and reduce travel times and costs.

The agenda and relevant documents of each SPAG meeting will be sent to members in advance of the meeting. Only agreed actions and decisions will be recorded at the meeting. These will be made available to all members of the SPAG within 2 weeks of the meeting.

All meetings and communications will be in English.

Other activities

Specific activities for the SPAG will be regularly defined, in line with EURORDIS' mission, strategy, and priorities.

Besides the regular SPAG meetings, SPAG members may be involved in any of the following activities:

- Contributing to EURORDIS' positions and supporting its contributions to consultations by the European Commission or other relevant EU and international institutions.
- Identifying key issues to be discussed and addressed within the scope of the SPAG's mission.
- Presenting at national or European events.
- Elaborating short reports on relevant barriers or policies in their country.
- Translating short summaries of key advocacy position documents.
- Contributing to dissemination and advocacy activities.
- Providing input to the delivery of projects and supporting the identification of opportunities to participate in projects and access grants.

Conferences

When participating in conferences or forums not specifically on behalf of the SPAG, members shall make clear that the views expressed are their own views and not those of EURORDIS and the SPAG.

When being invited as a EURORDIS-SPAG representative, members must inform the EURORDIS staff member responsible for coordinating and supporting the SPAG, who will appreciate whether it is appropriate for the member to participate and represent the SPAG. In this case, the SPAG members shall:

- Ensure that the views expressed are those of EURORDIS.
- Identify with their affiliations to their organisation as well as to EURORDIS.
- Report back to the SPAG on the outcomes and relevant aspects of the meeting.

Contact

EURORDIS will designate a EURORDIS staff member to coordinate and support the SPAG, who reports periodically to the Board on the activities of the SPAG. The specific contact will be shared in the Call for Expressions of Interest and on the EURORDIS' website SPAG page.

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, assist the preparation of agendas and minutes of SPAG meetings.
- Contribute to the identification of the experts.

Application Process

A Call for Expressions of Interest will be launched in 2023. A standardised form and online application process will be developed by EURORDIS.

The applications will be reviewed by the EURORDIS Social Policy and Initiatives Director. A maximum of 15 applicants will be selected and endorsed by the EURORDIS Board of Directors.

Useful resources

1. [EURORDIS Position Paper: Achieving Holistic Person-Centred Care to Leave no One Behind](#) (2019).
2. European survey [Juggling care and daily life: The balancing act of the rare disease community](#) (2017).
3. UN Resolution on [Addressing the Challenges of Persons Living with a Rare Disease and their Families](#) (2022).
4. EURORDIS [Answer to the EC Consultation on the European Pillar of Social Rights](#) (2016).
5. EURORDIS [contribution to the EC consultation on the Disability Rights Strategy for 2021-30](#) (2021).
6. EURORDIS [contribution to the EC call for evidence on the EU Disability Card](#) (2023).
7. EURORDIS [Contribution to the EC call for evidence on the proposal for a European Care Strategy](#) (2022).
8. EURORDIS [Factsheet: Work-life Balance Directive](#) (2019).
9. [Results of the EU-funded INNOVCare project](#), on integrated care for rare diseases (2015-2018).
10. Castro, R. *et al.* (2021). [Rare Diseases](#). In: Amelung, V., Stein, V., Suter, E., Goodwin, N., Nolte, E., Balicer, R. (eds) Handbook Integrated Care. Springer, Cham. https://doi.org/10.1007/978-3-030-69262-9_44
11. Castro R. *et al.* [Bridging the Gap between Health and Social Care for Rare Diseases: Key Issues and Innovative Solutions](#). Adv Exp Med Biol. 2017;1031:605-627. doi: https://doi.org/10.1007/978-3-319-67144-4_32. PMID: 29214594.

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 (± 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, scoping, 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.



05 11 2020

Doc. Ref. EURORDIS/mandate-DAG/20

TERMS OF REFERENCE FOR THE EURORDIS DIGITAL AND DATA ADVISORY GROUP

The EURORDIS Board of Directors endorsed, on 6 July 2019, the creation of a Digital Advisory Group (DAG) and approved the Terms of Reference describing the strategy and rules of procedure for the EURORDIS DAG. For clarity the advisory group has been renamed the Digital and Data Advisory Group.

Objectives, Mandates, and Rules of Procedures

1. MISSION

To recognise the potential of digital technologies, the data collected through them and artificial intelligence for people living with a rare disease and to understand that EURORDIS can play a role in bringing the voice of patients/ patient input into this area/activity.

To pursue opportunities for influence, strategic decision making, helping EURORDIS to assess and bring views of patients to highest level. To access funding opportunities.

2. GENERAL OBJECTIVES

The Advisory Group advises EURORDIS on all aspects regarding digital policies and procedures. Its role is:

- to inform EURORDIS on developments in the digital space and raise awareness within EURORDIS staff, members and volunteers of digital and data developments;
- to draw EURORDIS' attention to specific opportunities to bring the view of patients living with rare diseases to any relevant decision-making forum;
- to facilitate the participation of patients in relevant consultations by sharing and collecting contributions from patients and their organisations, comparing different methods for the involvement of patients;
- to contribute to EURORDIS consultations by the European Commission or other relevant EU and international institutions;
- to provide advice and where appropriate help pursue collaboration with the Global Commission to End the Diagnostic Odyssey for Children with a Rare Disease
- to help EURORDIS draft advocacy positions on digital issues, for ultimate consideration by the EURORDIS European Public Affairs Committee or the Board where necessary;
- to enable EURORDIS to bring the rare disease patient voice to specific projects and initiatives that we may get involved with
- to horizon scan with a view to help identify opportunities to participate in digital projects, or access grants either as EURORDIS or on behalf of our members; and to make recommendations on which opportunities are the most promising.

3. ACTIVITIES



Specific activities for the DAG will be regularly defined by the Advisory Group itself, with priorities set in close collaboration with EURORDIS. This should be a blend of proactive goals as well as reacting to opportunities and issues that emerge. The review of the value of this group and its ways of working will be reviewed after one full year of activity. The responsibilities of the DAG include a commitment to participate actively in the work of the group and to adhere to all relevant policies. (see section 10).

4. COMPOSITION of the DIGITAL AND DATA ADVISORY GROUP

The DAG will be composed of a **MAXIMUM of 14 representatives**, including the following:

- EURORDIS volunteers from Full and Associate Members of EURORDIS who fulfil the following criteria:
 - availability for a minimum of four to eight e-meetings and up to two face-to-face meetings per year. Please note, due to the situation with Covid19 the meetings will be held online in the foreseeable future;
 - strong interest in digital health as evidenced by relevant professional or volunteer experience or relevant training;
 - previous participation/willingness to participate in EURORDIS Open Academy subject to availability;
 - English language skills and the ability to work in English;
- The Advisory Group will also include a *maximum* of up to 4 members of EURORDIS staff serving in an ex officio capacity
- The Advisory Group will include external digital experts from EURORDIS partner organisations acting in the field. External representatives cannot exceed 50% of the group.
- The composition of the group will be reviewed after one full year of its establishment.

As representatives, staff, and volunteers are acting in their individual capacity, it is their responsibility to liaise with their organisation as necessary. It is also their responsibility to inform their organisation about the activities of the Advisory Group and their own membership.

Members of the DAG will be nominated for a term of 3 years; however, membership will be confirmed on a yearly basis based on participation and commitment.

On occasion discussion within the DAG may be subject to confidentiality, and when this is specified confidentiality must be respected by all participants.

5. MEETINGS

EURORDIS aims to organise a one-day face-face session at least once per year. The meeting place and date will be decided on a case by case basis, with a view to minimising cost and maximising convenience for all participants. Other meetings will be conducted by webinar. During the period of the Covid19 all meetings will be held online.

Expenses will be covered for EURORDIS volunteers where possible and when agreed in advance.

All meetings will be held in English.

6. EURORDIS' RESPONSIBILITIES



EURORDIS shall:

- Co-ordinate the work of the Advisory Group;
- Organise meetings (face to face, conference calls, video conferences) of the DAG, ensuring timely circulation of meeting documents;
- Ensure adequate co-ordination of the work carried out within the DAG;
- In relation with a DAG member, assist in the preparation of the agenda and minutes of the meetings of the DAG;
- Cover expenses of attendance of meetings for volunteers;
- Contribute to the identification of experts;
- Review existing communication tools and evaluate possibilities for new ones;
- Review adherence to the Code of Conduct and annual declarations on conflict of interest.

7. CONTACT

- The DAG will be co-ordinated by Veronica Popa, veronica.popa@eurordis.org.

8. CONFERENCES

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

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

In this case the DAG member:

- Shall ensure that the views expressed are those of the DAG;
- Will identify her/himself with its affiliations to her/his patient groups as well as to EURORDIS;
- Will report back to the DAG on the outcomes and relevant aspects of the meeting.

9. GUARANTEES of INDEPENDENCE and PREVENTION OF POTENTIAL CONFLICTS OF INTEREST

Any direct interests in the digital sector must be declared and, where necessary, volunteers and professionals with an interest must recuse themselves. 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.

10. CODE OF CONDUCT

The members of the EURORDIS DAG are EURORDIS volunteers and shall comply with the Charter of the EURORDIS Volunteers, which has been adopted by the EURORDIS General Assembly on 8 May 2014 in Berlin. All DAG members will be asked to sign a copy of this code.



EURORDIS Mental Wellbeing Partnership Network

Network Terms of Reference

June 2023

Introduction

People living with a rare and undiagnosed condition experience an accumulative impact on their mental wellbeing. At an individual level, people living with a rare disease (PLWRD) can have an associated mental health co-morbidity, whereas at a population level, the community lives with the increased psychological impact associated with the rare diseases journey across all stages of life. In addition, PLWRD and their families have increased exposure to social inequalities and discrimination, which are risk factors and determinants for poor mental wellbeing.

EURORDIS has established a Mental Health Partnership Network in order to take action to the rare disease community call to look beyond the physiological symptoms of a rare condition, with a specific focus on fostering increased access to psychological support as a fully integrated part of the coordination of care and ensuring it is routinely available at diagnosis and throughout the following care pathway.

Purpose

The EURORDIS Mental Health Partnership Network (Partnership Network) will bring together experts and stakeholders to drive a community action on mental health and wellbeing for PLWRD, their families and caregivers.

Specifically, the Partnership Network will unite and empower the rare disease community to come together, learn, take action and tailor recommendations to the specific needs of PLWRD in all policy areas, to ensure that the mental health and wellbeing of the rare disease community is improved. The findings of the Network will feed into EURORDIS' work across all policy areas, specifically through:

- increased access to quality preventative measures, early detection and treatment services, improving health promotion, and ensuring more people recover.
- tackle inequalities, stigma and discrimination among the rare disease community experiencing poor mental health and wellbeing.
- taking action to contribute to addressing the underpinning socio-economic and environmental determinants on mental health in the rare disease community.

Mission

Through collaboration of experts – medical, research and by lived experience, the Partnership Network will harness the collective evidence, innovations, best practices, tools and resources, and level up the capacities to shape policies and promote practices that reduce the impact of rare diseases on mental health.



General Objectives

The Partnership Network has been established to unite and empower the rare disease community to come together and take actions that promote good mental health and prevention of mental health distress and challenges, specifically to:

- network and share expertise and knowledge to better understand the relationship between rare diseases and mental health.
- provide input to EURORDIS work on addressing the health and social determinants of mental health and tackling stigma and discrimination.

Specific Objectives

The Network specific objectives are to foster a peer learning environment to lead on key actions and deliverables agreed under the EURORDIS Mental Wellbeing Initiative (Initiative), specifically:

- harness the community's expertise and experience, to build knowledge on the intersectional mental health and rare diseases needs and to strengthen systems locally in all sectors.
- engage the rare disease and mental health communities and survey the population needs related to mental health and wellbeing.
- increase awareness of the complexities and increased vulnerabilities of living with a rare disease and the associated impact of mental health and wellbeing on individuals and families.
- build competencies and empowerment of rare disease advocates, through peer learning training to engage in actions in all policies that address rare diseases and the mental health needs of the community.
- identify best practice and evidence-based approaches and develop a psychological wellbeing toolkit and standardised protocols that can be leveraged to prevent mental health co-morbidities through access to health promotion and prevention interventions.
- strengthen health system capacities to understand the intersectoral needs between rare diseases and mental health, to optimise policies, practices and interventions.

In addition, in collaboration with EURORDIS policy work, advise on the following issues:

- scientific and research aspects of the Initiative.
- strategies and position statements related to rare diseases and mental health.
- addressing the risk factors and determinants of mental health.
- dissemination of the findings to the wider community.

The Partnership Network will connect and partner with social, educational and employment experts from EURORDIS' Social Pillar Advisory Group and other EURORDIS Task Forces and Working Groups.



Composition of the Partnership Network

The composition of the Partnership Network will be approximately 50 members, from within both the rare disease community and the mental health sectors and associated fields.

Members can be from:

- Patient Organisations
- Hospital and Academic Institutions
- Research Groups and Networks
- Social Care Sector Organisation
- Education and Employment Institutions
- Non-Governmental Organisations
- National and Local Authorities & Policy Institutions

Membership is on a voluntary basis.

Members can be existing members of established EURORDIS advocacy groups, such as the Social Pillar Advisory Group, ERN Steering Committee or Task Forces. These can be formal or informal members of the Partnership Network. EURORDIS may co-opt additional members, as appropriate.

Members of the Partnership Network will act on an individual capacity. Members may nominate substitutes to attend meetings to contribute in an active and full capacity.

Partnership Network members agree to:

- adhere to the Terms of Reference of the Partnership Network and Charter of the EURORDIS Volunteers.
- 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 Partnership Network.
- actively participate in Network meetings and working groups and support the network to achieve its objectives, activities and outcomes.
- represent the views of the rare disease community and patient groups to the network activities.
- share knowledge, expertise and information, such as resources, evidence, best practices and case studies, with other participants.
- prepare ahead of the meetings, including reading in advance the papers provided for the meeting, so as to meaningfully contribute to the meetings.

Mental Wellbeing Champions will be identified from the membership of the Partnership Network and who would be recognised as EURORDIS volunteers and represent EURORDIS in key events and conferences.



Co-chairs

EURORDIS will coordinate the function for the Partnership Network and will have two co-chairs, one from the EURORDIS Board of Directors and the other to be the EURORDIS Mental Wellbeing Lead.

The co-chairs will be responsible for ensuring that the Partnership Network operates in such a way as to deliver its key function and report progress on the Networks activities to the EURORDIS Board of Directors.

Structure of the Partnership Network

The structure of the Partnership Network will consist of a **Steering Group** and **Working Group(s)**.

- A Steering Group will provide leadership and support to ensure successful delivery of the Partnership Network. The co-chairs will jointly chair the Steering Group.
- Working Groups can be established when required to support operational implementation of the annual work plans.

Please see Annex I for the role and function of the Steering Group, including the composition, responsibilities and processes for establishing the group.

The Partnership Network will connect and partner with social, educational and employment experts from EURORDIS Social Pillar Advisory Group and other EURORDIS Task Forces and Working Groups.

(a) Steering Group

The Steering Group will oversee the strategic development of the network and the implementation of the annual work plan and advise on advocacy and strategic issues and future priorities. The Steering Group will promote the adoption of a human rights approach, advancing equality and tackling inequalities, and ensure a full life course approach across all the activities of the Mental Wellbeing Initiative.

(b) Working Groups

Working Groups may be created to undertake specific tasks of the Partnership Network work plan. Each group will designate a lead and co-lead who will chair the meetings and report back to the Steering Group.

Meeting Frequency

The Partnership Network will meet 3 times per year to review the annual work plan, serve as a platform for knowledge sharing among participants and discuss key issues. Additional workshop sessions may take place to allow for focussed debate on key issues. Meetings will primarily be on a virtual basis to facilitate wider attendance and reduce travelling times.



The agenda and relevant documents of each Network Partnership meeting will be sent to members in advance of the meeting to allow for preparation. Only agreed actions and decisions will be recorded at the meeting by one of the co-chairs or lead. These will be made available to the members of the Partnership Network within 2 weeks of the meeting.

The Steering Group will meet every four months, to report on progress of the Working Groups, discuss issues and revise the work plan. The Steering Group will make recommendations that will be validated, where appropriately, by the EURORDIS Board of Directors. In the event that a consensus is not reached by the Steering Committee, the co-chairs of the Network will make the casting decision.

Each Working Group will have meetings, attended by Working Group participants. The frequency of working group meetings will be determined by the lead and co-lead of the respective Working Group.

The structure and frequency of the meetings will be kept under review to ensure that the Partnership Network remains effective.

Contact

The Partnership Network will be coordinated and assisted by Matthew Bolz-Johnson, Mental Wellbeing Lead & Healthcare Advisor. E-Mail: matt.johnson@eurordis.org

EURORDIS shall:

- coordinate the work of the Partnership Network.
- provide technical and scientific support.
- organise meetings of the Partnership Network, ensuring timely circulation of meeting documents.
- in relation with a Partnership Network member, EURORDIS will assist in the preparation of the agenda and minutes of the Partnership Network meetings.
- contribute to the identification of the experts.

Status

The Partnership Network is an informal network hosted by EURORDIS. The operations of the Network shall abide by these Terms of Reference as well as other relevant EURORDIS policies, specifically the EURORDIS Charter of the EURORDIS Volunteers.

Confidentiality & Potential Conflicts of Interest

Members will be expected to respect the confidentiality of meetings. Members will be expected to notify the co-chair or lead and exclude themselves from any specific item on the agenda where there is a potential conflict of interest.



Conferences

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

A member of the Partnership Network may participate in international conferences or other forums and represent the Network, upon request or official agreement of the co-chairs of the Partnership Network.

In this case the Network member:

- shall ensure that the views expressed are those of the Network.
- will identify her/himself with its affiliations to her/his patient groups as well as to EURORDIS. The final decision around whether or not it is appropriate for a member to participate and represent the Network will rely entirely on EURORDIS management (President and CEO).

Application Process

Community leaders, representatives and leading experts in their respective fields will be invited to join the Partnership Network on an ongoing basis.

A Call for Expressions of Interest will be launched in 2023. A standardised form and online application process will be developed by EURORDIS. Applicants should be endorsed by their organisation to join the Partnership Network and have experience and expertise in rare diseases and mental health.

Initially, all membership applications will be assessed and approved by the co-chairs of the Network. Following this, membership applicants will be notified of their membership approval (or otherwise) by the co-chairs of the Network. Subsequent applications submitted following the launch of the Network will be assessed and approved by the Steering Group.

Annual Review

The arrangements outlined within these Terms of Reference will be subject to further changes. There will be an annual review of the Terms of Reference.

Annex 1 Steering Group

The Steering Group will oversee the strategic development of the network and implementation of the annual work plan and advise on emerging issues and future priorities.

It will do this by:

- ensuring appropriate engagement of stakeholders including the wider public, people with lived experience, service users, families and carers.
- providing overall strategic direction, including supporting the development of the workplans and strategies to drive implementation for the duration of the EURORDIS Mental Wellbeing Initiative.
- overseeing the work of the Working Group(s) of the Partnership Network, agreeing upon priorities and action, reviewing progress and outcomes, to optimise the Partnership Network impact.
- approving Network membership applications.
- sharing learning and good practices on improving mental wellbeing.
- ensuring that all members are acting as advocates for the broader aims and aspirations of the Partnership Network.

The Steering Group will be comprised of approximately 10 members appointed by EURORDIS for an initial term of 2 years, with the possibility of renewal. These members will consist of the two co-chair of the Partnership Network and the lead and co-lead of the Working Group(s). The selection process to sit on the Steering Group will strive for balanced representation of the Partnership Network participants, with respect to sector and stakeholder group – experts by lived experience, clinicians and policy leads; and connect with social, educational and employment experts from the EURORDIS Social Pillar Advisory Group.

Steering Group decisions will be made through consensus of committee participants. The Steering Group will be chaired by the two co-chairs, one co-chair from the EURORDIS Board of Directors and the other co-chair will be the EURORDIS Mental Wellbeing Lead.

Rare Disease Day Governance

Adopted in February 2021

Objective of this memo

Rare Diseases Day is a well-established and long term programme of EURORDIS, growing in reputation and ambition, with more partners joining and their activities around the day expanding. The diversity of cultures is increasing while expecting a global voice, using strategic approach, offering a growing set of tools, adopting performance measurements to assess its impact, scaling up its human resource and financial allocation. Rare Diseases International (RDI) now plays a role in engaging its members in Rare Disease Day and organising international policy events. A more robust governance is needed for strategic guidance, inclusiveness of and co-creation with partners, autonomy in day-to-day operations.

There are two type of activities progressively more distinct on Rare Disease Day:

- The EURORDIS activities to support Rare Disease Day global campaign
- The EURORDIS activities to support the Rare Disease Day in Europe with the National Alliances and the EURORDIS specific policy events or communications

This paper outlines proposals to enhance the governance of Rare Disease Day formed by 3 concentric circles and the Coordination Team:

- The Rare Disease Day Global Network of Partners – formalization of the network, enhanced role
- The Rare Disease Day Outreach Group – continuation of current role, enhanced representation
- The Rare Disease Day Steering Committee – new, delegation from the Board of Directors, inter-linked with Outreach Group and Global Network of Partners

The EURORDIS Board of Directors keeps the same final responsibilities of Rare Disease Day.

Committee	Description	Meeting frequency/ communications means	Topics / responsibilities
Rare Disease Day Global Network of Partners	National Alliances who are Member organisations of EURORDIS or RDI	Partner newsletter emails Webinars One meeting online per year Microsoft teams	Champion the campaign in their country, monitor use of the Rare Disease Day logo in their country, respond to surveys and report needs and concerns to the steering committee
Rare Disease Day Outreach group	Volunteer representatives from the NA partner organisations – new members join annually (no limit) – must be appointed by their organization to represent organization views	Meetings online 4-6 times per year, approx. once a month from June – December Microsoft Teams	Input to the annual campaign in-progress , marketing materials and video. They share experience, of their national campaigns, inputting in the messaging, bringing cultural and local sensitivities in addition to the diverse rare disease patient perspective

Steering Committee (NEW)	NA representatives (representative of min. 4 of 6 WHO regions) + EURORDIS BoD rep, CEO, COO, Communications Director, RDI Executive Director, RDI Council Member rep + External attendees can be invited	Meetings 3 times per year – ½ day – currently online 1. April 2021 2. July 2021 3. October 2021 Microsoft Teams	This group will recommend the strategic direction for the campaign 1-5 years ahead : monitor the strategic orientations including the purpose, the cause, the call to action, the target audiences, the messaging, the framework of tools for the campaign; consider the sustainability of the campaign, partners and opportunities.
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Overview and context

Rare Disease Day is coordinated on a global level by EURORDIS with currently over 60 National Alliance patient organisation partners.

Evolution of Rare Disease Day partner patient organisations

2008 – EURORDIS and 18 National Alliance member organisations

2009-2019 – EURORDIS, European National Alliances members of EURORDIS (CNA) + international National Alliances with signed MoU with EURORDIS

2020-today – EURORDIS, National Alliance Members of both EURORDIS and RDI

National Alliance patient groups (members of EURORDIS and RDI) agree to both champion the campaign in their respective countries, but also contribute to the decisions of the cause and call to action, messaging, materials and purpose of the campaign, ensuring a truly global voice.

This structure has served us well and the campaign has made significant achievements in the last several years. There are, however, very recently several significant developments that have given the campaign new potential:

- The completion of a well-received strategic review from Hill & Knowlton in 2018-2019
- Significant increase in capacity due to new funding from CZI in 2020-2022, enabling the appointment of an additional EURORDIS staff member for the campaign and more communication resources
- Successful steps to making the campaign more global and less Europe and North-American centred

Managing a co-creation process with 60 partners has proven challenging.

Rare Disease Day Steering Committee (RDDSC)

The role of the Steering Committee, which will include representatives of the global national partners as well as EURORDIS staff and leadership engaged in the campaign, is to oversee the strategic plan and major operational decisions of the Rare Disease Day campaign.

Concretely, in the short-to-medium term that means the Steering committee will have the following role

- to work towards building a sustainable and truly global campaign instigating change for people living with a rare disease and their families.
- to review the strategic priorities developed with H&K strategies review
- to bring forward National and local needs and cultural considerations to support the global campaign.
- to monitor and contribute towards the 1-5 year strategic plans which include deciding the purpose, cause and call to action for future campaigns

- to propose and review the overall framework produced for the campaign; the target audiences; the messaging
- to identify, clarify and define the impact we want the campaign to achieve; revise the partnership framework
- to define the performance measurement (outcomes and metrics) and assess the impact

Composition of the Steering Committee

The Steering Committee should have between 14-17 members. Members should commit to attending all of the meetings scheduled and show global representation.

1. 4 ex officio posts from EURORDIS
 - Chief Executive Officer, EURORDIS (Has day-to-day strategic oversight of the campaign)
 - Chief Operating Officer, EURORDIS (Has day-to-day operational oversight of the campaign, responsible for sustainability)
 - Strategic Communications and Marketing Director EURORDIS
 - 1 EURORDIS Board member (provides the link back to EURORDIS Board, who ultimately have governance responsibility for the campaign – ie. Simona Bellagambi)
2. Two ex-officio posts from Rare Diseases International
 - Executive Director + Member of the RDI Council (pushes the campaign to think globally)
3. 7-8 RDD National Alliance members:
 - Based on a Call for Expression of Interest. The team will encourage applications.
 - There should be committee members from at least 4 of the WHO regions* though we'd encourage the broadest geographical diversity possible. The Steering Committee will look to co-opt new members to ensure continued geographical diversity / representation
 - If there are more than 10 volunteers, the Rare Disease Day global network of partners may be asked to vote or EURORDIS will submit a list of names, representing all regions of the world*
 - The national alliance members look to ground the campaign in the diverse realities of national coordinators, bring the expertise gained in their countries, and serve as a bridge between the Steering Committee and the national alliance partners
 - The term of steering committee is 3 years
 - We recommend this representative be the person in charge of communications or operations of the Rare Disease Day events and outreach campaign within the organisation
4. 1-2 additional members may be co-opted by EURORDIS staff to join the Steering Committee for one or more meetings, depending on needs for the campaign and the discussion. These members could be representatives from organisations outside of EURORDIS and National Alliances with experience in areas like international health awareness campaigns, marketing, media and press for example.

Meetings of the Steering Committee (RDDSC)

- The Steering Committee (RDDSC) meets virtually 3 times per year. Two ½ day strategic meetings and one shorter meeting in July.
 - March/April-to analyse the previous campaign and make suggestions for the future
 - July to discuss feedback on or select the creative concept, to discuss the plan for the following year including the tools and metrics
 - September to review and sign off the draft communications plan
- Microsoft Teams will be used as a tool to share materials and exchange with the group

- All RDDSC members commit to actively participate; and only send deputies in very limited circumstances

Management of the Steering Committee

The Steering Committee meetings are designed and coordinated by the Communications Director are being prepared by the Rare Disease Day Senior Manager and supported by the Communications Junior Manager.

Rare Disease Day Global Network of Partners

The 60 National Alliance partners will be engaged as both champions of the global campaign at the national level, but also participating in the global campaign activities (capacity building webinars, surveys, etc), news and digital publications (ie. Tell Your Story, publishing events, sharing social media, using marketing materials). The national alliance members of the steering committee will play a more visible role and will elect the members of the steering committee.

Annual structured feedback will be organized by the coordinating team and sent to all partners to measure in a qualitative manner to identify the points of progress of the program and the performance of the past campaign.

EURORDIS communication and awareness team

The team has two functions: the management of the global campaign with the network of partners and the management of the campaign in Europe.

The EURORDIS global campaign team is responsible for the strategic development and planning, the operational planning and budgeting, the day to day operational management of the campaign, the smooth and effective governance, and to make timely operational decisions where required.

EURORDIS recognises it has an important, but separate role, to mobilise and support its National Alliances in Europe to get the most out of the opportunities presented by Rare Disease Day. This includes coordinating policy actions in Europe with the National Alliances and other European members like programs such as Rare Disease Week for National Alliance Members to meet with MEPs and hosting a policy event in Brussels (the Rare 2030 closing event in 2021). This coordination will continue to be discussed through the Council of National Alliances meetings which are already in place twice a year.

Outreach Group (former Working Group)

National Alliances can choose to be more implicated in the annual campaign marketing materials, including the campaign video, as they have been doing since the start in 2008. They contribute by volunteering to participate in the Outreach group, working with the Rare Disease Day coordinating team to give feedback on the annual campaign materials, input into messaging, priorities for toolkits and webinars.

There are currently, in preparation of the 2021 campaign, 15-20 national alliance partners who have volunteered to be part of the working group, and we thank them for their continued participation in this group. We ask them to continue their mission, responding to the exchanges in Microsoft teams and attending discussion meetings as needed (1 hour maximum) to input in the campaign materials and video script.

The members of the Outreach Group are directly approached by the team.

Currently, this group is heavily European (10 of the 15 attendees) which does not offer an equal global balance that the campaign needs (ie Strategic review).

We will work to balance the group with half from Europe and then the other half regions of the world. Ideally, there will be a mix of large and small countries and who are the most active with their communication and participation in EURORDIS activities.

1. Simona Bellagambi (EURORDIS Board Member)
2. Anne-Sophie Blanchard (France)
3. Bianca Paskal-Leptien (Germany)
4. Carolina Cobos (Spain)
5. *Comunicazione* (Italy)
6. Dorica Dan (Romania)
7. Farhana Ali (UK)
8. Sarah Weiler (Luxembourg)
9. Tamara Kvas (Croatia)
10. Ulrike Holzer (Austria)
11. Celia Palacios Gomez Tagle (Mexico)
12. Laura Mullen (US) or Lesli Nordstrom (US)
13. Roberta Anido De Pena (Argentina)
14. Sarah Cannata (Australia)
15. Yukiko Kuroda Nishimura (Japan)

Launching the Steering Committee (RDDSC)

We suggest holding the first exceptional meeting for the Steering committee in **April 2021** looking ahead at 2022.

Draft Agenda items:

- Monitor implementation of recommendations from the H&K strategic review
- Cause, Purpose and Call to Action for 2022 + Specific ambitions
- Appointment / Call for members
- Adopt the Performance Measurements (outcomes and metrics) for 2022 campaign
- New Rare Disease Day website for 2022

We suggest that EURORDIS conducts an open call for members to all of the 60+ National Alliances in March 2021. Depending on the response, the ex-officio members of the RDDSC will select the 7-10 partner members, favouring a balance of regions. For example, those members could be

1. European representative
2. North America representative - Laura Mullen (US) or Lesli Nordstrom (US)
3. Latin America (Aliber?)
4. Sarah Cannata (Australia)
5. Asia – for example - Yukiko Kuroda Nishimura (Japan) or Rachel Yang (China)
6. Africa - Christine Mutema (Kenya)
7. Gulf region?

Review of the Governance of Rare Disease Day

The Terms of Reference for the Rare Disease Day partners and then for the RDDSC should be reviewed by the RDDSC at the end of the 2022 campaign and any proposed changes discussed. Any substantive change to the guidance needs to be approved by the EURORDIS Board of Directors.

Next steps

- Discuss and agree the above by the Board.
- Share with current volunteers for information
- Discuss internally for implementation
- Inform RDI Council and invite for comments

- Feedback on the above will be taken into consideration, we will produce official terms of reference for the Network, the Outreach Group and the Steering Committee and review the Terms of Reference for official partners to see if any updates are required. This will be done in parallel to the preparation of 1st SC meeting.

*(The Americas (includes North and south), Africa, East Mediterranean (incl some on N Africa and the middle east), Western Pacific, Southeast Asia and Europe)