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Orphan Medicinal Products
in the service of patients
affected by rare disorders

Programme of community
Action on Rare Diseases
(PARD)



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Promote a european policy for the patients

**EURORDIS was created in 1997 in France
and is today a coalition :**

- ◆ **more than 190 associations and several
National Alliances (7)**
- ◆ **from 14 european countries
(Belgium,Denmark, France, Germany,
Greece, Iceland, Italy, Ireland,
Netherlands, Portugal, Spain, Sweden,
Switzerland, UK)**
- ◆ **Several millions of patients**



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EURORDIS mission

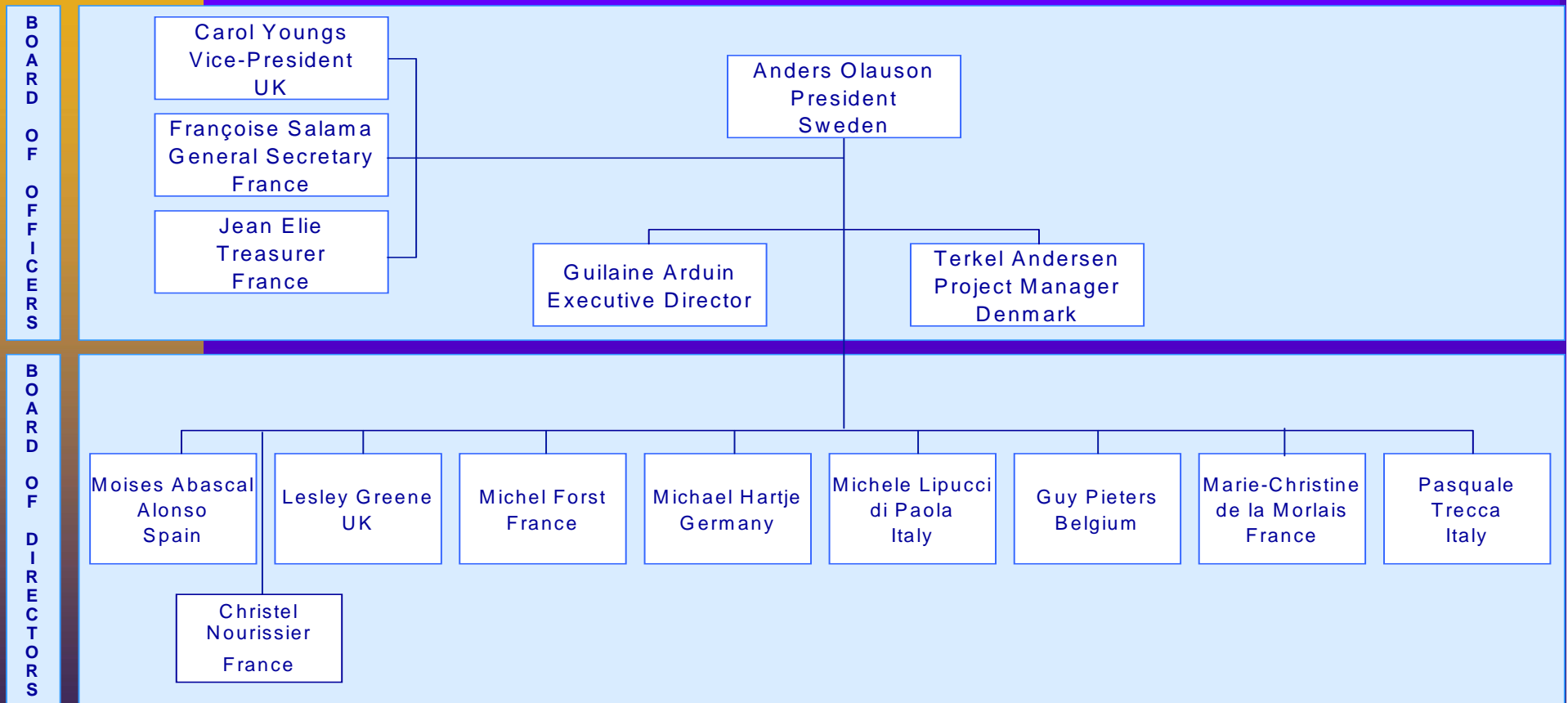
- ◆ **Promote Rare Disorders at European level**
- ◆ **Advocate for information availability to those affected by rare disorders**
- ◆ **Promote research and access to new therapies**
 - ✓ **Out of 3 seats reserved for patients organisations, 2 were nominated by EURORDIS and appointed to the COMP (Committee on Orphan Medicinal Products)**



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Organization Chart of EURORDIS

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Global Project of PARD

Belgium

Denmark

France

Germany

Italy

Netherlands

Portugal

Spain

Sweden

UK

Share Best Practices
across Borders and
Pathologies

To be developed
To be developed
European Portal R Disorders
Orphan Medicinal Products

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Regulation On Orphan Medicinal Products

COMP

ADOPTED !

PARD IV

PARD III

PARD II

PARD I

2005

4 years

2000

5 years



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Objectives of PARD I

- ◆ **To strengthen existing national alliances (Denmark, France, Germany, Italy, Spain, Sweden, UK)**
- ◆ **To strengthen collaboration at Community level among associations on rare disorders**
- ◆ **To develop new national alliances in European countries, around the theme of orphan medicinal products (Belgium, Netherlands, Portugal)**
- ◆ **To develop partnerships among all alliances**



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Objectives of PARD I (continued)

- ◆ **Identification of needs and problems regarding Orphan Medicinal Products in each country (7)**
- ◆ **Share best practice and knowledge**
- ◆ **Elaborate action plans in the field both at national and european level**
- ◆ **Report evaluation needs**
- ◆ **Produce recommendations at national and European level**
- ◆ **Issue a document on « Access to Orphan Medicinal Products for Rare Disorders in Europe ».**



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Plan of action - PARD I

- ◆ **Phase I : Kick-off meeting in Brussels - October 20th, 2000**
- ◆ **Phase II : Explore the situation at national level - Workshop in 7 member states**
- ◆ **Phase III : Develop common understanding - Workshop at european level**
- ◆ **Phase IV : implement different actions - workshop at national level**
- ◆ **Phase V : Final phase - write guidelines, recommendations for EC.**



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Phase I - Kick-off meeting

- ◆ **Kick-off meeting Brussels, October 20th, 2000**
- ◆ **Participants : Coordinators of 7 national alliances and 3 potential alliances (*Belgium, Denmark, France, Germany, Italy, Netherlands, Portugal, Spain, Sweden, UK*)**
- ◆ **Objectives : To give methodology training to allow each national alliance to develop workshops in their countries, to give them instructions to fulfill their commitments in order to achieve final goal and send results to EC.**



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Phase II - National Workshop

- ◆ **Guidelines developed by EURORDIS and partner Gemini Consulting**
- ◆ **Brainstorming on similar questions regarding “Orphan Medicinal products”**
- ◆ **7 national alliances involved (Denmark, France, Germany, Italy, Spain, Sweden, UK)**
- ◆ **2 days workshop (January - February 2001)**
- ◆ **Recommendation reports written by each national alliance after the workshop**



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National Alliances Commitments

Methodology

Guidelines

- ◆ To strengthen existing national alliance
- ◆ To develop partnerships among all alliances and more specifically with potential national alliances (Belgium, Netherlands, Portugal)
- ◆ To share best practices and knowledge
- ◆ To develop workshops at national levels (2) and european level (1)
- ◆ To speak freely, to create synergies
- ◆ To generate concrete actions at national level
- ◆ To report evaluation needs, make a list of problems
- ◆ To make a synthesis in each national alliance
- ◆ To produce recommendations at national level

Keep deadlines

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Results



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Phase III - European Workshop

- ◆ **2 days workshop in Brussels**
- ◆ **Participants : 7 national alliances, 3 potential alliances representatives (around 50 persons)**
- ◆ **Results of national workshops, recommendations, plan of action**
- ◆ **Round Table, open discussion with Pharmaceutical Industries, representatives of WHO and COMP**
- ◆ **Selection of recommendations to be delivered to the European Commission.**



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Main goals of PARD I

- ◆ **To summarize recommendations at European level**
- ◆ **To reinforce structure of existing alliance**
- ◆ **To strengthen collaboration at Community level among associations on Rare Diseases**
- ◆ **To create 3 new alliances (Belgium, Netherlands, Portugal)**
- ◆ **To create partnerships among all alliances**



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Conclusion

- ◆ **European team spirit has started with kick-off meeting**
- ◆ **Each national Alliance has successfully developed national workshops (January/February 2001)**
- ◆ **Potential alliances are well on track**
- ◆ **European Workshop is scheduled on June 7th, 8th, 2001**

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