

EUROPLAN

European Project for Rare Diseases National Plans Development

Coordinated by the Italian National Centre for Rare Diseases

Italian National Institute of Health

2012-2015



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EURORDIS' activities for National Plans - a long-standing commitment

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EURORDIS and RD National Plans

EURORDIS has been a leading actor in the process aimed to design, adopt and implement national policies on RDs.

In this presentation:

1. Paving the way for NPs
2. Common guidelines for NPs- EUROPLAN I
3. Towards tailor-made plans- EUROPLAN II



1. Paving the way for NPs

Preparing the ground

- EURORDIS was closely involved in the development process of the **1st French National Plan for Rare Diseases (2005-2008)**, that pioneered comprehensive national policies on rare diseases.
- EURORDIS general secretary was actively involved in the evaluation of the 1st French Plan and the implementation of the 2nd Plan, consolidating the outcomes of the 1st.
- 2nd European Conference on Rare Diseases (Luxembourg, 2005) - EURORDIS proposes a “White Book” on Rare Diseases to initiate a European policy/legislation on rare diseases.
- Autumn 2006 - EURORDIS endorses the creation of a EU group in charge of drafting a status report, serving as possible basis for future EU policy/legislation on rare diseases and coordination of policies and actions between Member States.
- Since July 2007, EURORDIS was an active member of the drafting group that led to the proposal for a Commission Communication.

1. Paving the way for NPs

The Commission Communication on Rare Diseases (CCRD)

- The CCRD thrust and endorses national plans on RD.

Communication from the European Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions : “Rare Diseases: Europe’s challenges” - 11 November, 2008

“Member States base themselves on a common approach for addressing rare diseases, based on existing best practice, through the adoption of a Council Recommendation.

The Commission's proposal for a Council Recommendation accompanying this Communication recommends that Member States put in place strategies organised around...putting in place inter-sectoral action national plans for rare diseases.”

- EURORDIS extensively contributed to the public consultation : clear support to the adoption of national plans and specific contribution on certain areas (research, centres of expertise, CAVOD, social services and patient empowerment).
- EURORDIS mobilised all its members and stimulate their comments with special focus on National Alliances and European Federations.

1. Paving the way for NPs

The Commission Communication on Rare Disease (CCRD)

«Do you agree with the idea of having action plans?

Yes, a national public policy on rare diseases - embodied in a National Plan with concrete commitments in terms of actions, budgets and timelines and effective management - is an essential tool to improve the lives of people living with rare diseases. The NPRD aims at integrating all activities and initiatives on RD at national and regional levels. The EU should recommend the adoption and coordination of NPRD according to the CCRD.

European guidelines for the elaboration of the NPRD would be very useful.»

Extract from EURORDIS contribution to public consultation on the CCRD, 14 February 2008

1. Paving the way for NPs

Preparing the ground

- November 2008 - EURORDIS launches, co-organises and co-funds the meeting in Paris under the EU French Presidency “**National Plans and Strategies for RD in Europe: towards common recommendations**”.
Objective to : **To promote the concept, rationale and benefits of National Plans on RD in EU countries.**
 - ➔ Identify strategic drives likely to be shared between the different Member States.
 - ➔ Provide incentives for national policies for RD to converge and join together with EU-wide policies in an articulate manner.
 - ➔ Stimulate the adoption of the Commission Communication on RDs and the Council Recommendations, which thrust and endorse the adoption of National Plans
- The meeting prepares the ground for the Council Recommendation on RD and consolidates methodology and approach of EUROPLAN conferences.



1. Paving the way for NPs

The Council Recommendation

Council Recommendation on an Action in the field of Rare Disease - 9 June, 2009

- Creation of **the European Union Committee of Experts on Rare Diseases (EUCERD)** in November 2009; includes 27 Member States + 4 EURORDIS patient representatives + 4 industry representatives + healthcare & research representatives
- **Recommendation to implement national plans or strategies for rare diseases in all EU Member States by the end of 2013**

- EURORDIS was involved in the drafting process of the Commission proposal for a Council Recommendation.
- Active Advocacy and support from Members of the European Parliament, including supporting the appointment of the Parliament's Rapporteur.
- Working for the adoption of the Recommendation with the French Health Ministry in view of the French Presidency of the EU in 2008.
- Coordinating the advocacy to national Health Ministries via its National Alliances, in view of the Council adoption.



2. Common guidelines for NPs - EUROPLAN I

EUROPLAN I

EUROPLAN I 2008-2011 - “European Project for Rare Diseases National Plans Development”

- **EURORDIS is the only patient organisation partner in EUROPLAN I.**
- Actively involved with partners in the development process of key deliverables - EUROPLAN Recommendations and EUROPLAN Indicators;
- Responsible for a full Work Package - “**WP8 - Promoting the recommendations for Rare Diseases National Plans and presenting the Commission Communication on Rare Diseases**”.
- EURORDIS involved **15 National Alliances (NAs)** to organise **15 national conferences.**

2. Common guidelines for NPs - EUROPLAN I

Bottom up approach

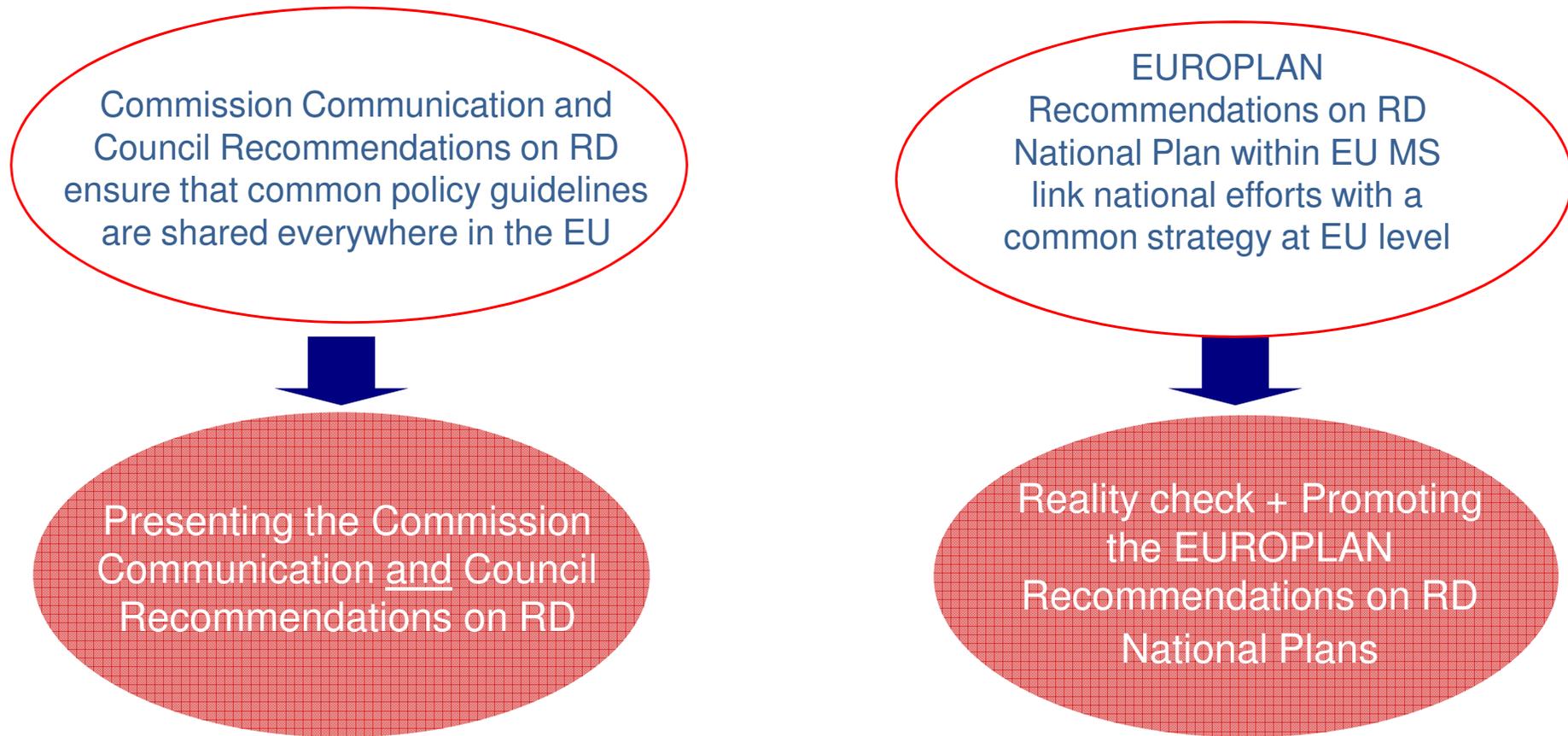
EUROPLAN national conferences - **stirring the process from down to up:**

- National Conferences organised by the **National Alliances (NAs) of patients' associations** (patient-centred policy; well coordinated common methodology across EU).
- The identification of NAs resulted from a **Call for Expression of Interest and reciprocal engagements** of EURORDIS and NAs -including the commitment to involve national stakeholders.
- The appointment of **6 Advisors** (representing National Alliances) facilitated the link EURORDIS and NAs and the EU-national communication flow.
- The conferences benefited from an overview of the 7 themes of the Council Recommendation while bringing in the RD community **to relay local needs to national and EU authorities.**



2. Common guidelines for NPs - EUROPLAN I

A common methodology



National Conferences' main objective reflects this double combined approach: help prepare a high quality National Plan on RD with concrete objectives in each field - including those elements which may integrate with the EU policy on RD



2. Common guidelines for NPs - EUROPLAN I

A common methodology

- National Conferences organisers involved **national authorities** as well as **all other stakeholders** all the way from the preparation of the conference and Steering Committee to the conference attendance.
- **Same format** for each conference = unity of the project in Europe.
- Preparation of a **common content** and common issues to be addressed in each conference - same powerpoint presentations presenting each pillar of the Council Recommendation.
- Same **template for 15 national reports** and a final synthesis report.



2. Common guidelines for NPs - EUROPLAN I

National Conferences - where, when & who

COUNTRY	CITY	ORGANISER	NUMBER of PARTICIPANTS	DATE	ADVISOR
BULGARIA	Plovdiv	NAPRD National Alliance of People with RD	352	28-29-30 May	Dorica Dan
CROATIA	Dubrovnik	Croatian Society for RD	180	17-18-19 September	Christel Nourissier
DENMARK	Copenhagen	Rare Disorders Denmark	81	19 November	Britta Berglund
FRANCE	Paris	Alliance Maladies Rares	153	30 September	Christel Nourissier
GERMANY	Berlin	ACHSE	190	13-14 October	Mirjam Mann
GREECE	Athens	PESPA	199	26-27 November	Simona Bellagambi
HUNGARY	Budapest	HUFERDIS	138	15-16 October	Dorica Dan
IRELAND	Dublin	GRDO	169	20 January 2011	Avril Daly
ITALY	Florence	UNIAMO	120	11-12-13 November	Simona Bellagambi
NETHERLANDS	The Hague	VSOP	80	18-19-20 November	Mirjam Mann
POLAND	Krakow	Foundation MATIO	64	22 October	Christel Nourissier
ROMANIA	Bucarest	RONARD	178	18-19 June	Dorica Dan
SPAIN	Burgos	FEDER	116	5-6 November	Simona Bellagambi
SWEDEN	Stockholm	Sällsynta diagnoser	84	11 November	Britta Berglund
UK	Manchester	Genetic Alliance UK - RD UK	86	16 November	Avril Daly



2. Common guidelines for NPs - EUROPLAN I

National Conferences' key facts and results

- Over 2200 participants with representatives of main stakeholders groups (so distributed by % of attendance):

– Public authorities:	14% (up to 22% in Spain)
– Academics /researchers:	20% (up to 30% in Hungary)
– Healthcare professionals:	14 % (up to 29% in France)
– Industry:	10% (up to 22% in UK)
– Patients:	39% (between 33% and 44%)

- Different stakeholder sat around the same table to discuss RD policies, in some countries for the first time!



2. Common guidelines for NPs - EUROPLAN I

National Conferences' key facts and results

- Helped RD communities awareness that **national efforts are “embedded” into a more comprehensive and long-term approach** integrating EU and national levels.
- Specific recommended actions and national measures have been **integrated into the debate and the language of stakeholders** participating to the Conferences.
- The whole experience of EUROPLAN proved to be an **outstanding awareness-raising exercise** in the field of rare diseases at the national level.
- To conclude: **National Conferences created momentum favourable to the development or advancement of overall national policies on RDs at national level.**



3. Towards tailor-made plans - EUROPLAN II

EUROPLAN II - Building on success

- Overall success of EUROPLAN I experience and method - many countries **expressed their interest in having a 2nd national conference** to further discuss the measures of National Plans, their assessment or implementation, their sustainability.
- EURORDIS is the only partner in the EUCERD Joint Action ‘Working for Rare Diseases’ that is not a member state institution but a NGO.
- EURORDIS is involved in the continuation of the work started in EUROPLAN I (WP4 - “EUROPLAN II”) - **supports and coordinates National Conferences on RDs to be organised by National Alliances/patient groups.**
- Ultimate goal is to contribute to the adoption of a plan or strategy for rare diseases in all EU Member States by the end of 2013.



3. Towards tailor-made plans - EUROPLAN II

Identified countries

To date, **24 countries** have been identified where EUROPLAN II national conferences will be organised:

- **19 EU member countries** :

Belgium	France	Luxembourg	Slovakia
Croatia	Greece	Netherlands	Spain
Cyprus	Hungary	Poland	Sweden
Denmark	Ireland	Portugal	United Kingdom
Finland	Italy	Romania	

- **1 more EU country to be recruited**

- **5 non EU countries** (ad hoc arrangements: support to National Conferences in line with EUROPLAN methodology + EURORDIS own funds):

Georgia	Serbia	Ukraine
Russia	Switzerland	



3. Towards tailor-made plans - EUROPLAN II

Identified countries - flexibility

- Once the 25th EUROPLAN country has been identified, the list of countries could be expanded as to include additional EU countries.
- New EU countries could join the EUROPLAN process and organise a EUROPLAN national conference under specific conditions:
 - No budget support and support by EURORDIS Advisors...
 - ... but tools, content and format can be shared and used, visibility ensured as “EUROPLAN conferences”.
- For these countries, where a patient NA does not exist, **other subjects different from National Alliances are invited to initiate the process.**



3. Towards tailor-made plans - EUROPLAN II

Identified Advisors

10 EUROPLAN Advisors have been selected to work on EUROPLAN II :

EURORDIS Advisors	National Alliance	Countries
Avril Daly	GRDO; Genetic and Rare Disorders Organisation	Ireland
Maria Gardsater	Sällsynta Diagnoser, Rare diseases Sweden	Sweden, Finland
Christel Nourissier	Alliances Française Maladies Rares, France	France , Switzerland
Dorica Dan	RONARD; Romanian Alliance for Rare Diseases	Romania, Hungary, Slovakia
Lene Jensen	RDD; Rare Disorders Denmark	Denmark, Belgium, Portugal
Lily Cannon	CARD; Cyprus Alliance for Rare Disorders	Cyprus, Luxembourg
Oleg Kvlividze	GeRad; Georgian Foundation for Genetic and Rare Diseases	Georgia, Ukraine, Russia
Simona Bellagambi	UNIAMO; Italian Federation for Rare Diseases	Italy, Spain, Greece
Stephen Nutt	Rare Disease UK	United Kingdom, Netherlands
Vlasta Zmazek	Croatian Alliance for Rare Diseases	Croatia, Serbia, Poland



3. Towards tailor-made plans - EUROPLAN II

Expanding the existing methodology (1)

Building on the overall success of EUROPLAN I, the same methodology is proposed with new elements:

- **Integrated EU/National** - Promote EU reference documents on RD policy & assess their transferability at national level via the involvement of NAs and their Advisors + **promotes spill over effect by involving 5 non EU countries.**
- **Comprehensive** - Across all 7 main themes **and extending to new measures** (mainly EUCERD recommendations).
- **Multi-stakeholders** - Involve all stakeholders, broadest possible outreach. **Better opportunity to reinforce links with national authorities.**



3. Towards tailor-made plans - EUROPLAN II

Expanding the existing methodology (2)

- **Long-term** - Sustain grassroots movement in favour of national plans or strategies for RDs **looking at a 2nd or more generation of National Plans** and at their sustainability over the years.
- **Tailor-made** - **Each conference programme will be tailored to the different existing national policies on RDs and national healthcare systems:**
 - With the assistance of its EURORDIS Advisor, each National Alliance prepares a programme proposal based on the common content guidelines and adapted to the national situation and needs.
 - In particular, the following will be considered: whether a NPs exists or not, the status of development of a national plan (inception, advanced draft, adoption, implementation, evaluation, 2nd generation of NP...), current debate and recent national measures...



3. Towards tailor-made plans - EUROPLAN II

Timeline

January 2012

- Call for Expression of Interest on the part of National Alliances and Advisors

March 2012

- EUCERD Joint Action Kick-off Meeting

May 2012

- Presentation of project at European Conference on Rare Diseases and Orphan Products in Brussels, Belgium

August 2012

- Selection of Advisors completed

September 2012

- Identification of selected countries completed
- **Inception Workshop WP4**

September-October 2012

- Consultation with EURORDIS leaders and volunteers, Advisors and constituents of EJA on content guidelines

October 2012

- Content Guidelines and Layout of Conference documents distributed for developing conferences projects.
- Begin development of tailor-made conferences

November 2012 - December 2014

- **National Conferences take place**

February 2015

- Final Reports submitted to ISS



3. Towards tailor-made plans - EUROPLAN II

Challenges ahead

- **Different level of development of national policies** - proposing a common format that helps countries at different stages of the National Plans' development process.
- **Bringing in new countries-** Involving and mobilising relevant stakeholders from EU countries not yet involved in the conference process.
- **Integrating new measures** - Incorporating new policy measures adopted over the past years into the conference content material so as to stimulate a up to date discussion.
- **Integrating measures adopted by EJA/WP4** while the national conferences are being organised.



In conclusion

Rare Disease patients at EU and national level:

- Had and have a **leading role** in
 - **Designing the main EU documents and guidelines** (content and methodology);
 - **Adopting policy measures** for rare disease patients;
 - **Implementing and adapting** them to national healthcare systems.
- Sustain the process of development of RD National Plans via a **bottom-up approach**.
- Work **synergically** to implement an **integrate approach between EU and national level**.
- Bring in a vision for National Plans' **long-term sustainability**.



THANK YOU !

To get involved in the EUROPLAN II National Conference in your country, please contact EURORDIS' National Alliances:

<http://www.eurordis.org/content/national-rare-disease-alliances>

or EURORDIS: valentina.bottarelli@eurordis.org

To learn about rare diseases at a glance, please watch our Rare Disease Day video: <http://www.rarediseaseday.org/solidarity>

