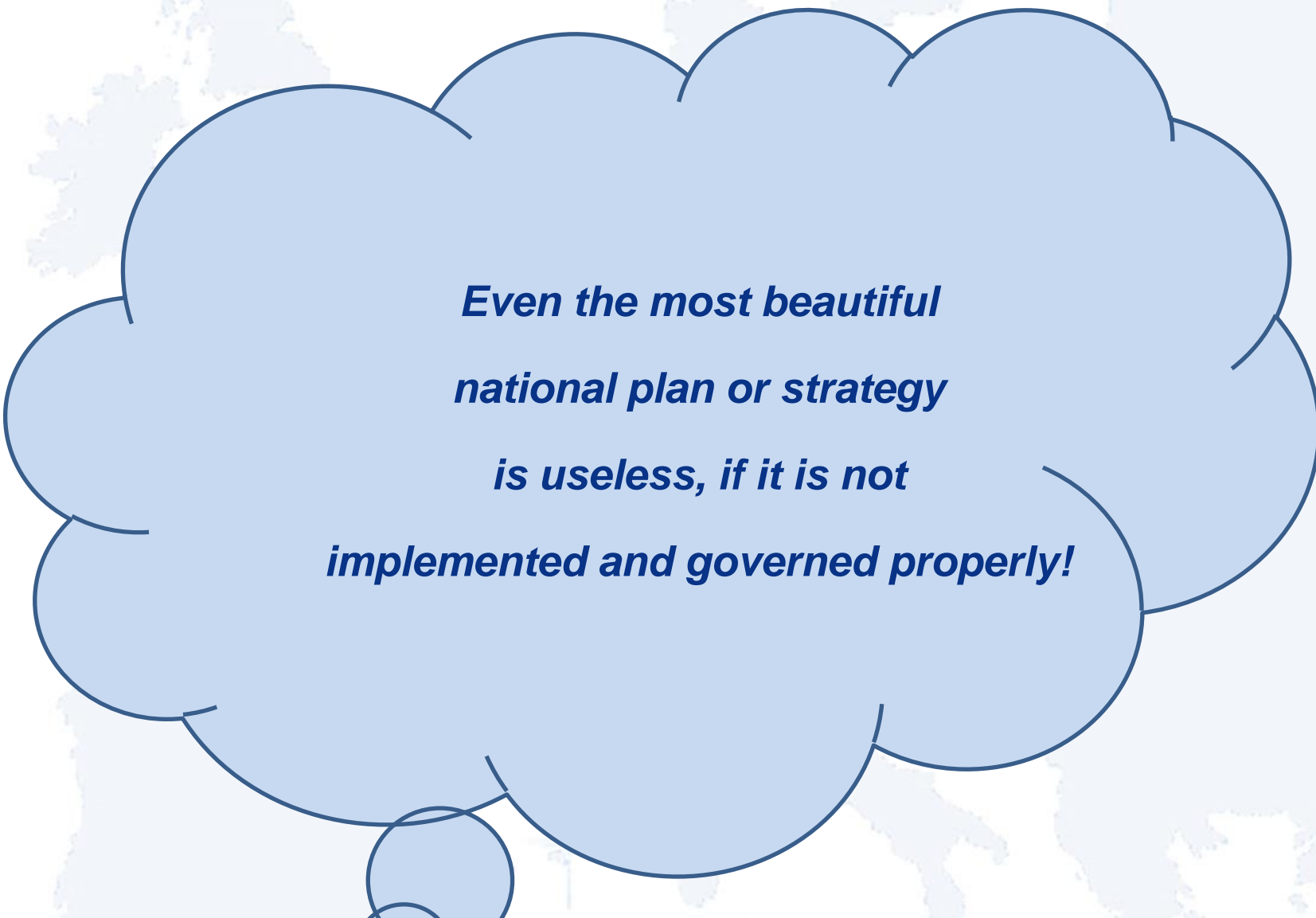




## Best practices in governance and monitoring of National Plans/Strategies

- Lene Jensen, EUROPLAN Advisor

# Governance of National Plans for Rare Diseases



***Even the most beautiful  
national plan or strategy  
is useless, if it is not  
implemented and governed properly!***

# Governance of National Plans for Rare Diseases

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- A specific budget

# 1. Governance of the NP / NS

## **EUCERD Core Indicators for NP/NS:**

2. Existence of a RD advisory committee
3. Permanent and official patients' representation in plan development, monitoring and assessment



## **EUROPLAN Guidelines Recommendations:**

(Establishment of) a mechanism (e.g. interdisciplinary panel, committee) including relevant stakeholders to be established to assist the development and implementation of the National Plan or Strategy

# 1. Governance NP: Multistake holder body

## **GOOD PRACTICE:**

A multistake holder body oversees the implementation of the NP.

→ Key stakeholders participate in the governance of Plan.



**HR, GB, SK, DE, PL, CY, FI,  
RO, ES (proposal: HU)**

### **Composition:**

- Health Ministries & sometimes Min. for Social affairs, education, research
- Regions representatives
- Academics, experts & learned societies
- Industry representatives and/or their associations
- Insurers, national agency for pharmaceutical products
- Patients representatives

### **Role:**

- Supervision of Implementation
- Advisory role
- Decision making role

# 1. Governance NP: Governing body

FR, DE, ES, CY

## GOOD PRACTICE:

The structure of the governing body is sometimes more complex and based on a multi-tier model, as in Germany, Spain or France, or organised in working groups, as in Cyprus..

## EXAMPLES:

**FRANCE** - A “Committee for monitoring and orientation” (COSPRO) oversees the follow-up of the measures decided under the Plan 2011/2014.

- MoH general director responsible for the Plan (chair) + stakeholders.
- A Secretary General is commissioned by the Health Ministry to implement the Plan and cooperates with the president and the scientific vice-presidents for « science » and « research ».

**CYPRUS** - A National Committee for RDs is responsible to oversee the implementation and the monitoring of the National Strategy on RD.

- The Committee meets every one or two months and its members meet in 5 Working Groups, in each topic area of the NP: prevention/early diagnosis, treatment, social inclusion, research, registries/codification.
- The National Alliance CARD is represented with 13 other members.



# 1. Governance NP: patient representatives

HR, GB, PL, CY, FI, RO, ES

## GOOD PRACTICE:

Patient representatives are full members of governing body with decision making powers

- acknowledgement that patients are engaged in governing bodies, that they have a say on measures that concern them directly
- ensure accountability

## EXAMPLES:

**GREAT BRITAIN** - UK Rare Disease Stakeholder Forum, established to develop the UK Strategy for RD, ensured that each nation implements all commitments. Chaired by a patient representative.

**ROMANIA** - RONARD established a partnership with the MoH, the framework for developing and then implementing the Romanian NP. RONARD was instrumental in setting up the governing body (National Council for RD), initially funded by a technical assistance grant given to RONARD, and only later received an institutional role.



## 2. Monitoring of the NP / NS



### **EUROPLAN Guidelines Recommendations:**

- The National Plan or Strategy to have a duration of 3 to 5 years. An intermediate deadline is established, after which, an evaluation process is undertaken and corrective measures are adopted.
- For longer time scales or no defined time frame, a 2- to 3-year cyclic evaluation and adaptation process is adopted, if needed.
- The NP or NS is to be monitored and assessed at regular intervals using, as far as possible, EUROPLAN indicators.
- The implementation of the actions and their achievements should be assessed.
- The most appropriate evaluation of a National Plan or Strategy is to be done by an external body and takes into account also patients' and citizens' views.
- Patients' needs should be assessed at the beginning and the end of the plan implementation using the same methodology.
- Evaluation Reports are made public.



## 2. Monitoring of the NP / NS

### GOOD PRACTICE:

FR, FI, ES

**A specific body is responsible to monitor the implementation of the NP**

**FINLAND** - The Steering Committee firstly created by the Min. of Social Affairs and Health to elaborate the NP, that includes representatives of HARSO, the Finnish National Alliance of RD POs, has now the role of monitoring and evaluating the NP.

### GOOD PRACTICE:

HU, FR, ES

**Indicators are used to monitor the NP implementation and measures are accompanied by deliverables and timelines.**

**HUNGARY** – Action envisaged in the National Plan are accompanied by clear deliverables and measurable results in the form indicators.

→ Clear timeline shows start & end dates of all priority actions with specific deliverables.

→ The EUCERD recommended 21 Core Indicators will be used to monitor the implementation of the NP plus some EUROPLAN Indicators.

**SPAIN** – The NS is broken down in 13 general + 37 specific objectives, each with technical recommendations and monitoring and evaluation indicators. The NS will act as a framework for the different regions, in charge of implementing the Strategy's measures.

# 3. Sustainability of NP / NS

## **EUCERD Core Indicators for NP/NS:**

- 18. Existence of a policy/decision to ensure long-term sustainability of the RD plan/strategy
- 19. Amount of public funds allocated to the RD plan/strategy

## **EUROPLAN Guidelines Recommendations:**

- Appropriate resources to be allocated to ensure the feasibility of the actions in the planned time.[...]
- Measures to be taken to ensure the sustainability, transfer and integration of the actions foreseen by the national plan or strategy into the general health system of the country.



# 3. Sustainability of NP / NS

## GOOD PRACTICES:

**A specific budget is allocated to the NP/NS that is not blended in the broader national health budget.**

**Usually, activities are broken breakdown; for each of them, budget, responsible institutions and potential sources of funding are identified.**

**BE, FR, RO, HU**

**FRANCE** – 86 MEUR over 3 years

→ Substantial parts of this budget are allocated to:

- Orphanet
- the Fondation Maladies Rares (coordination of research in the RD area)
- National help line
- National Data Bank on Rare Diseases
- Restructuring of centres in more coherent health networks.

**HUNGARY** – 3,022,600 EUR /7 years

→ Each primary action has cost estimates w. financial resources.

→ Different financial sources are different: most of the budget lines use of Structural Funds 2014-20 is specified.

**BELGIUM**

→ 200.000 EUR /year for the management of the NP, plus  
→ some 10 key actions in the Plan have a specific budget allocation, for a total of approx. 7,5 MEUR.



### 3. Sustainability of NP / NS

IT

**GOOD PRACTICES:** National /regional budgets: a specific amount of the National Health Fund is set aside for RD and redistributed to Regions.

**ITALY** – No specific budget allocation for NP (to be implemented using Regional budgets, the Regions being responsible to provide health services in the Italian NHS).  
→ However, the NP establishes that “specific amounts of the National Health Fund may be put aside for actions in support of planning, service organisation, monitoring and training initiatives within ‘the RD system’”. → NB not additional budget, requires a specific legislative measure to be adopted.  
→ e.g. in 2010-2012, 20 million EUR/year were allocated to RD related expenditures.

**GOOD PRACTICE:** The use of European Structural Funds is specifically planned and the NP incorporated in the agreement with the EC (Operational Programmes) .

**HUNGARY** - Under the new Structural Funds (ESIF) a Human Resources Development Operational Programme had been adopted. The Hungarian Minister of Human Resources promised that the Hungarian RD National Plan will get support from the source of this last Operational Programme (October 2014).

HU



## 4. Dissemination & communication of NP/NS

### **EUROPLAN Guidelines Recommendations:**

- Information on the National Plan or Strategy to be made accessible to the public and it is disseminated to patients' groups, health professionals' societies, general public and media, making the plan known also at European level



## 4. Dissemination & communication of NP/NS

FR

**GOOD PRACTICE:** The status of implementation of the measures envisaged in the NP is presented on a regular basis.

**FRANCE** – The presentation of measures implemented in the framework of the Plan take place at least twice a year by the Committee for monitoring and orientation (COSPRO): information on the progress of the plan + opportunity to suggest adaptations as the need arises.

**Ad hoc meetings are also held to divulgate the progress of the plan implementation to broader audiences.**

**FRANCE** – Half-way through the Second French NP (Dec 2012), an “**information and experience sharing meeting**” on the implementation of the Plan for over 300 participants, esp. all the coordinators of the 131 Reference Centres  
→ to share information with the coordinators and patients’ association on the progress on the NP;  
→ to present and discuss in part. the new evaluation procedures for Reference Centres.



## 4. Dissemination & communication of NP / NS

BE, HU, ES

**PROPOSAL:** National Conferences proposed specific procedures or tools to ensure regular information on the NP implementation

**BELGIUM** – Regular feedback and provision of information should be ensured among authorities and stakeholders in ALL phases : planning identification of new measures to implement the NP, preparatory works, etc.

**HUNGARY** – MoH plans specific communication on the Rare Diseases NP within the project “*Development of public health communication*”, supported by the EU Cohesion Fund → a public report should be produced on the Steering Committee’s activities, on the outcome of its goals and on the activities of persons with key responsibilities.

### SPAIN

- Specific task forces or working groups activities in different areas of the Strategy should be providing information and updates on the NS.
- Greater awareness should be ensured via social networks and with the help of key opinion leaders publicising the Strategy.

# WHAT TO DO NOW?

*Learn more about Best Practice from EURORDIS, report not ready yet, but coming up*

*Have a look at the EUROPLAN recommendations, the indicators and the Best Practice and compare to State of the Art in your country*

*Give Feed back to EURORDIS –  
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