WORKING TOGETHER WITH PATIENT GROUPS

Nicola Bedlington

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Vienna

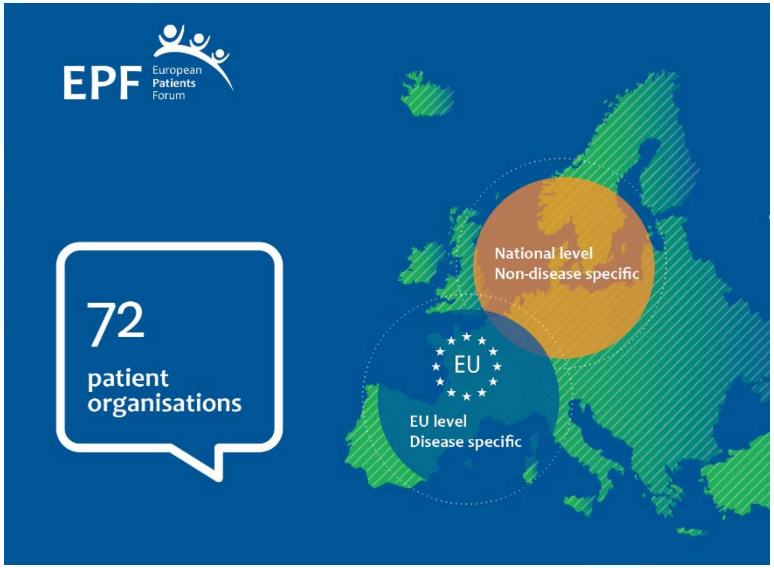
“A STRONG PATIENTS’ VOICE TO DRIVE BETTER HEALTH IN EUROPE”

EPF European Patients Forum

About EPF

- European Patients’ Forum
  - Umbrella organisation
  - Active since 2003
  - Independent & non-governmental
  - Europe’s patients’ voice

- Our members
  - 72 patients’ groups
  - Disease-specific EU & national coalitions



Vision and Mission

Our Vision!

“All patients with chronic conditions in Europe have **equal** access to **high quality**, **patient-centred** health and related care.”

Our Mission!

“to be the collective, influential patient voice in European health and related policies and a driving force to advance patient empowerment and patient access in Europe.”

This presentation

Working Together with Patient Groups

- Context – science is moving rapidly
- New initiatives on Patient Education , Patient Engagement, Patient Focused Medicines Initiative
- Emerging “strategies on patient engagement” EFPIA, IMI, DIA, ISPOR
- Need to clarify and consolidate relationship between industry and POs- drawing on existing Codes, Guidance, and new climate
- EPF’s complementary work to ensure an enabling and ethical environment

PARADIGM: A new era of patient involvement in R&D

Patients Active in Research and Dialogues for an Improved Generation of Medicines

Research and priority setting

Design of clinical trials

Early dialogues with regulators and HTA bodies

Target populations will be:

-Patient representatives (**adult**)

-Vulnerable populations

- **Children** and **young people** through the involvement of the Young Person Advocacy Group (YPAG);
- **Alzheimer Europe** (EPF member).

Our objectives

to provide a framework that allows structured, meaningful, sustainable and ethical patient engagement

Our vision

patient education and training	guidance on engagement	sustainability *in terms of concept, resources and processes.*

structured, meaningful, sustainable and ethical patient engagement

1st Open Forum + Expectations, needs and aspirations + 2nd Open Forum + Metrics + Sustainability roadmap + PE Toolbox + 3rd Open Forum = PARADIGM 30 months

Working together with patient groups

efpia

WORKING TOGETHER WITH PATIENT GROUPS

September 2017

Developed by the EFPIA Patient Think Tank

- This document, endorsed by EFPIA Board and EPF Board in 2017, supports patient organisations, companies, associations and external stakeholders that are considering collaborative efforts to improve the lives of patients.
- This document, the first of its kind in Europe, was co-created by representatives of Patient Organisations and the research-based pharmaceutical industry through the EFPIA Patient Think Tank with support from EFPIA's Ethics and Compliance Committee.
- The *EFPIA Ethical Principles and EPF's framework for cooperation* have been key drivers for the development of this paper.

Aim of this publication

- Outline the rationale for interactions between the pharmaceutical industry and Patient Organisations
- Suggest the principles, deriving from EFPIA Ethical Principles, and EPF's framework for cooperation, on which these interactions should be based
- Outline the points of collaboration through the life cycle of a medicine
- Discuss some of the challenges and potential solutions
- Provide a list of resources to support meaningful/appropriate collaboration

How does it fit in with EFPIA PO Code?

Since the EFPIA Code on Relationships between the Pharmaceutical Industry and Patient Organisation (PO Code) was developed, there has been a **significant shift in the world and encouragement for more collaboration between consumers, patients and the industry.**

This paper is **an additional point of reference** to guide these interactions, and to **complement the PO code.** It is not binding and does not overrule more restrictive law and regulations.

This document is not intended to be an exhaustive document but rather a useful reference point.

Who should use this document?

- All partners in the healthcare equation who would like to understand the rationale for collaboration
- Representatives of the pharmaceutical industry in Europe who are looking to collaborate with POs in different phases of medicines development
- Patient Organisation Representatives who are working on collaborative projects with industry or looking to collaborate

Rationale for the interactions: WHY

- Listening to patient experiences, patient challenges and exchanging insights can shape future of medical research and disease management to more adequately address the unmet needs of patients.
- it is only through open and transparent dialogue between patient organisations and industry that we can ensure that the patient perspective becomes an integral part of how medicines are researched, developed and delivered to patients. Appropriate inclusion has the potential to co-create and co-develop better patient outcomes.

Principles for engagement: HOW

Clarity of purpose

Legitimate need identified in advance/Being clear on the purpose but also the desired outcome

Transparency

Aims & objectives/Financial relationship

Independence

In all aspects/To ensure credibility/Funding from multiple sources

Respect

Mutual respect/prioritizing long term commitment/valuing each other's contribution

Non-Interference

In the HCP/patient relationship

Engagement across the life-cycle of a medicine: WHAT

EPF European Patients Forum

- **Patient engagement happens at each step of the cycle of a medicine**

- **It can be:**
  - Direct engagement between companies and patient groups
    - **For example when contributing to study design in the context of clinical trial**
  - Exchange of information between companies and patient groups to build understanding, but the direct engagement is between patient group and regulator or HTA bodies
    - **For example at the initiative of Regulatory Authorities in the context of Marketing Authorization, participation of patients in scientific/protocol assistance procedures**

  - *The EFPIA 2017 Health Collaboration Guide is a good source of examples*

Potential hurdles and proposed solutions

- The Working Together with Patient Groups document is intended to be used and give guidance throughout Europe.

- In the same time, the Patient Think Tank has recognised that different countries and regions might face some specific challenges.

- These specific challenges can be identified through national round-tables, to discuss potential solutions and share best practice examples among the relevant stakeholders (representatives of national patient organisations and from the national industry associations and companies).Feedback and conclusions from the roundtables will be brought back to the Patient Think Tank.

- If necessary this can lead to adding some regional or country- specific recommendations to the paper “Working together with patient groups”.

COMPLEMENTARY DOCUMENTS FROM EPF

The ADDED VALUE OF PATIENT ORGANISATIONS

TRANSPARENCY GUIDELINES

Rationale

Why a Report on the Added Value of POs?

- **Say who we are -** to dispel the confusion that sometimes exist around patient organisations and differentiate them from other stakeholders;
- **Building the trust -** to position patient organisations as legitimate stakeholders and reliable partners;
- **"Our contribution is wider than that"** - to raise awareness and highlight the added value they have in different areas (beyond medicines development);
- **Responding to criticisms -** to respond to the regular hostile comments towards civil society organisations, without being complacent.

About the Report

Methodology

Written by two external consultants

Data emanates from a survey conducted by EPF between September 2016 and February 2017 (35 respondents);

8 interviews: patient organisations, Civil Society Europe, MEPs, IMI, EMA, Robert Madelin, Industry partners…;

Desk Research

Letter to Juncker (and #EU4HEALTH)

Transparency Guidelines

About the Report

Target Audience

- EU & national decision-makers (MEPs, DG SANTE, Council);
- Health professionals;
- Payers;
- Industry;
- Patient organisations at different levels (for their own advocacy).

Structure of the Report

Main Roles of Patient Organisations

- Policy and Advocacy
- Capacity-Building & Education
- Peer Support
- Research, Technology and Innovation

Key Findings

Policy & Advocacy

- They provide the "**end-user perspective**"- POs help policy-makers understand the experience of living with a disease or condition;
- **Active at all stages of policy development** and in a range of institutional settings;
- Work across a range of policies;
- Contribute to a more **nuanced and balanced policy-making**.

80% of respondents are active in advocacy activities at European level

Top 4 advocacy activities reported:

•Monitoring policies and informing members (72%);

•Responding to consultations (72%);

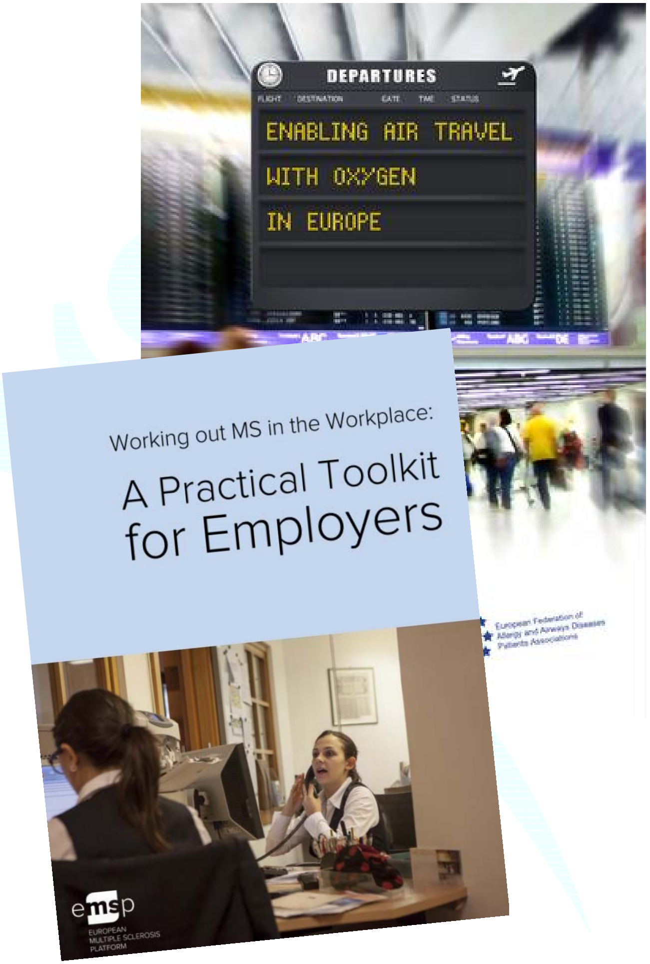
•Meeting with decision-makers (76%);

•Participating in advisory bodies (EU or national) (76%).

Key Findings

Capacity-Building & Education – POs as Capacity-Developers

- POs work towards strengthening the **organisational management** and governance of their constituencies;
- **Capacity-building targeted at:** their members, but also industry, policy-makers, academia and the media (through dissemination of info, educational initiatives, conferences…);
- POs play a key role in promoting and advancing **health literacy** – making sure information provided to patients is both of a high quality and accessible - (Especially true in the era of digital health information).



DEPARTURES

ENABLING AIR TRAVEL
WITH OXYGEN
IN EUROPE

European Federation of Allergy and Airways Diseases Patients Associations

Working out MS in the Workplace:
A Practical Toolkit for Employers

emsp
EUROPEAN MULTIPLE SCLEROSIS PLATFORM

Key findings

Peer Support

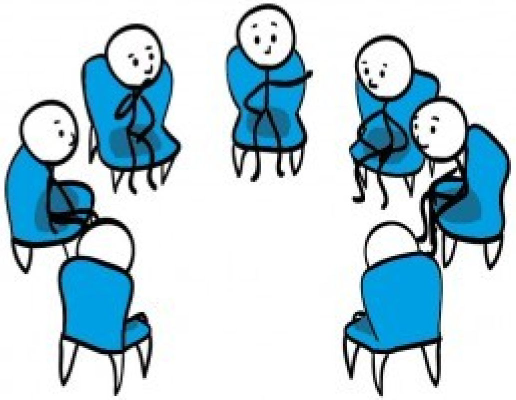
- Support targeted at individual patients.

Consists mainly of:

- Peer mentoring;
- Counselling or listening services;
- Legal and financial support.

(Mostly by national coalitions or local patient organisations, but not only).

37% of respondents offer support of some sort to individual patients



Key Findings

Research Technology and Innovation

- Data collection, reports, studies…

EURORDIS RARE DISEASES EUROPE

Europe-wide survey on the social impact of rare diseases

Alzheimer Europe

Benchmarking exercise on national dementia policies

- Co-design, development, application and monitoring of disruptive innovations for healthcare;
- Pharma research and development: from tokenism to involvement from the early stages and priority-setting;
- Increasing the capacity and capability of patients to understand and contribute to medicine research and development (ex: EUPATI).

Challenges

- Lack of resources & funding, lack of unrestricted funding;
- **Objectivity** (??);
- **Credibility & alleged lack of independence**;
- **Professionalisation vs. representativeness;**
- Overcoming the culture of tokenism;
- **Lack of performance measurement** – or rather lack of knowledge on how to measure the impact of patient organisations?

Some reflections and key messages

- “The approach to **scrutiny** placed on patient organisations to provide evidence of their added value and impact is **not routinely** applied to other heath stakeholders such as the pharmaceutical industry, health insurers or health professionals’ associations.”

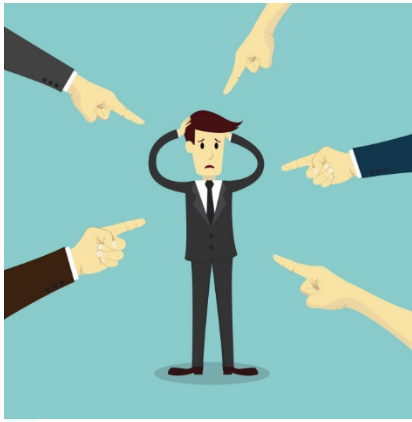
- “**Healthcare systems in Europe needs to be built in cooperation with patients as end-users**, and on the principle of shared responsibility for preventing diseases at community and society level: the value of patient involvement in policy and research should be clear to all, and such involvement should become an objective in itself”.

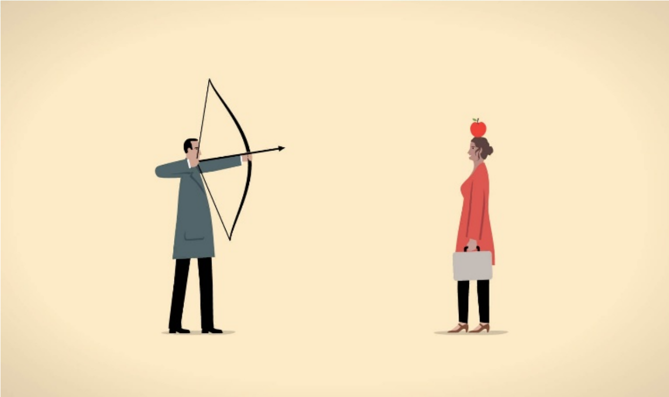
Transparency Guidelines

@eupatientsforum

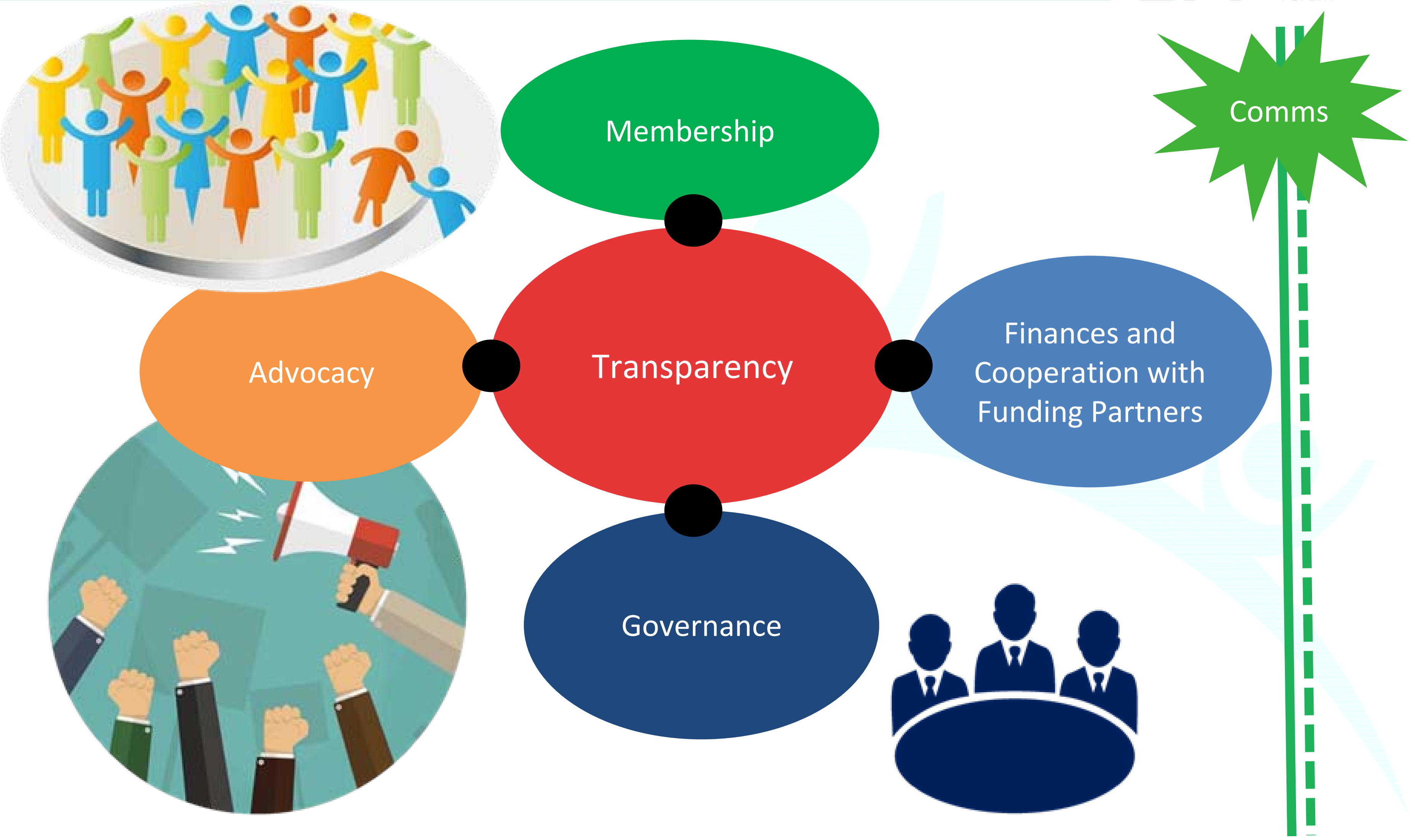
Scope and Objectives

- Not a "blame and shame" game, but supporting and guiding patient organisation's efforts
- Developing a common understanding of what constitutes an ethically sound patient organisation
- To reflect on the accountability of patient organisations, and how to demonstrate it
- To ensure the highest possible standards for our own network
- To increase the level of trust from other stakeholders
- A learning process for us too!





Transparency – beyond funding



Membership

Advocacy

Transparency

Finances and Cooperation with Funding Partners

Governance

Comms

Conclusions

- Working Together has addressed a key gap in articulating why and how industry and patient groups can work together
- It reflects a new progressive climate where patient engagement is more than ‘ a nice thing to do’ and could be transposed in other health industry sectors
- Patient groups are becoming more sophisticated and strategic : evidence on our added value- and also practical tools to ensure the highest standards of ethics and integrity

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www.eu-patient.eu

info@eu-patient.eu