

# PATIENTS AS PARTNERS FOR THE SAFETY OF INNOVATIVE MEDICAL DEVICES

Nicola Bedlington  
EPF Director

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

# About the European Patients' Forum



- Independent, non-governmental umbrella organisation set up in 2003
- **VISION:** All patients in the EU have equitable access to high quality, patient-centred health and social care
- **MISSION:** To ensure that the patient community drives health policies and programmes
- **MEMBERS:** disease-specific EU & national coalitions – 61 member organisations



# Patient safety: a core priority



- Our philosophy “everyone’s business” an open and transparent “patient safety culture” where healthcare organisations are “learning environments”

- **EC Patient Safety & Quality Working Group**

- EC Communication (2008) and
- Council Recommendation (2009)



- **Advocacy: EU legislation**

Eg. Pharmacovigilance, Medical devices

- **EU Projects on patient safety**

- EUNetPas (2008-2011)
- Joint Action PaSQ (2012-2015)



- *Building partnerships and collaboration* with WHO, health professionals, other stakeholders

# The changing role of patients



- Patients moving from passive recipients of healthcare to **active, involved & politicised** actors
- Patient-centredness** is a key operating principle of EU health systems
- EPF: involvement of patients in patient safety & innovation needed both at individual and collective levels
- As users who also have expertise as a result of managing chronic conditions in everyday life, patients have a key role to play in contributing to safety and quality of devices, from the innovation process and the clinical evaluation, to post marketing vigilance.

## Individual patients:

- Individual patient's experience of his/her healthcare "journey"
- Rich resource of information about gaps and failures in the system

## Patients organisations:

- role in informing & educating patients and health professionals
- Effective advocacy through access to the community

# Providing feedback on medical devices

- **At individual level:**

- A vital feature to improve vigilance system in the new proposal for Regulation in the EU: Direct reporting by patients & healthcare professionals.
- Collecting information about incidents, including these caused by user errors: to improve our knowledge of devices

- **At organisation level:**

- Patients' key role in the debate **on new EU Regulation to call for patient safety as a core priority.**
- Feedback on key safety issues: scrutiny for high risk medical devices, regulation of reprocessing of single use devices, call for better notified bodies, improved and more transparent clinical evaluation.

# Informing and empowering patients



- Patient organisations play a core role in developing and communicating quality, unbiased information including on benefit and risks of treatments available to patients
- Devices – especially new & innovative devices such as apps etc will increasingly require empowered patients
- Example from the European Parkinson's disease association:
  - “Parkinson's essentials” and “parkinson's in depth”: online information and decision aids for patients with user friendly information on deep brain stimulation and all other treatments, explaining their risks, benefits and contra-indications, questions to ask to healthcare professionals etc...

<http://www.epda.eu.com/en/parkinsons/essentials/>

<http://www.epda.eu.com/en/parkinsons/in-depth/>

# Participating in innovation

- EPF strongly believes that **people focus innovation**, rather than technology focused is essential for sustainability, better health outcomes, and to tackle, not exacerbate health inequalities
- Evidence of **benefit of a collaborative approach, with patient involvement from the development stage** to ensure better trust and confidence of patients new technologies

(<http://www.chainoftrust.eu/>  
<http://www.renewinghealth.eu/> )





# Participating in innovation

- Patients can bring key expertise on their real life needs & challenges, and ethics issues to take into consideration :  
example of Alzheimer Europe’s report “The ethical issues linked to the use of assistive technology in dementia care”
- provide guidelines on issues such as :
  - consent
  - training of patients and carers,
  - taking into account benefits for the patients when developing technology,
  - Eligibility criteria to consider to ensure access

<http://www.alzheimer-europe.org/EN/Ethics/Ethical-issues-in-practice/The-ethical-issues-linked-to-the-use-of-assistive-technology-in-dementia-care>

# The Patient Medtech Dialogue



- Established in 2011 first ever structured get-together of the Medical Technology industry with patient organisations
- bi annual meeting of EPF and EUCOMED members, 6<sup>th</sup> edition in November 2013
- Aim in our Memorandum of Understanding:
  - to develop patient-centred healthcare models in the sphere of medical devices.
  - exchange information on respective positions on important policy developments at EU level
  - develop best practices to uphold the highest ethical standards in the patient-industry relationship, based on independence and transparency.

# The Patient Medtech Dialogue (2)

- Evolution from a platform to exchange perspective to a structured dialogue with concrete actions planned ahead

Concrete deliverables:

- A patient focused Session in 2013 MedTech Forum
- Ongoing development of a checklist to define what is a patient centred company/ patient centred approach to innovation



- Launched Feb '12, runs for 5 years, 30 consortium members, PPP of EU Commission and EFPIA
- will **develop and disseminate objective, credible, correct and up-to-date public knowledge about medicines R&D**
- will **build competencies & expert capacity** among patients & public
- will facilitate **patient involvement in R&D** to support industry, academia, authorities and ethics committees





## EUPATI Certificate Training Programme

- Academic Modular Certificate Programme
- Patient Ambassadors in committees, R&D teams, ...
- Patient Journalists raising awareness
- Patient Trainers for patient communities & networks

**100**  
**patient**  
**advocates**

## EUPATI Educational Toolbox

- Educational tools for patient advocates
- Variety of distributable formats: Paper-based booklets, presentations, eLearning, webinars, videos etc.

**12.000**  
**patient**  
**advocates**

## EUPATI Internet Library

- Patients & lay public at large, e.g. on specific aspects of the development process of medicines for patients with low (health) literacy.
- Wiki, YouTube, films and/or cartoons

**100.000**  
**individuals**

# Final thoughts

- Patients are willing and able to contribute to the innovation process and to the safety chain
- Increasing recognition that patient centeredness is essential in healthcare innovation
- Working together in a **collaborative approach** including patients, professionals, researchers, industry and decision makers we can ensure patients have access to the safe and innovative device they need



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[www.eu-patient.eu](http://www.eu-patient.eu)

[info@eu-patient.eu](mailto:info@eu-patient.eu)

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