Getting Regulation and Innovation right
The patient's perspective

Nicola Bedlington

Who Are We?

- Independent, non-governmental umbrella organisation set up in 2003
- **VISION:** High-quality, patient-centred, equitable healthcare for all patients in the EU
- **RAISON D'ETRE:** To provide a strong and united patients' voice –> patients at the centre of EU health policy & programmes

51 member organisations – 150 million patients with chronic conditions across the EU

Medical Devices: A Patient's perspective

- **Medical Devices crucial for Patients with Chronic Diseases**:
  - Life expectancy + Quality of Life
  - Chronic diseases self -management approach
  - Reducing hospitalisation : Home Care
  - key role in meeting future health challenges
- **Need for a stronger framework to achieve this**
- Fostering innovation centred on patients and end-users' need
- Ensuring patients' access to high quality, safe and effective medical devices

EPF and medical devices: milestones

- Input to Commission Consultation (2008)
- Medical Device Exploratory Exercise (2009): **Information to Patients**
- High Level Conference on Innovation and Medical Technology
- 1st Patient MedTech Dialogue (May 2011) -**Sharing our perspectives**
- Feedback into Council Conclusions on innovation in the medical device sector**: Patient safety** a core priority in EU legislation

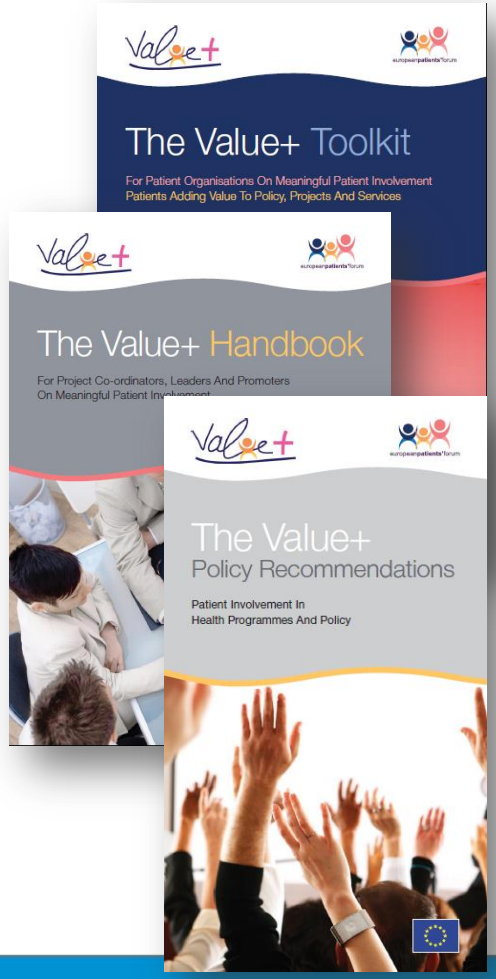
Next Steps: Discussions with Commission - Position Paper following - membership consultation

Medical Devices Recast: our priorities

- Information to Patients and Transparency
- Improving clinical evidence
- Strengthening conformity assessment
- Improving coordination in the EU
- Equitable access to medical devices for patients

Patient involvement in medical devices innovation

- EPF's model of meaningful patient involvement in health related research projects and policies.
- *Value + Resources*: www.eu-patient.eu
- Benefits of patients involvement : Patient real life experience, **Higher trust and confidence,** dissemination
- EPF's experience : Chain of Trust & Low Tech-High Tech workshop conclusions



Improving clinical evidence

- Clinical evidence is crucial for patient safety & access
- Clinical data from pre-marketing studies and post-marketing experience: transparent + more frequent collection of data
- Improve notified bodies expertise to analyse data (Council Conclusions)
- Encourage patient, families, and users involvement in the manufacturer's R & D (Council Conclusions) –> identify patients' needs + ensure usability of device.

Strengthening the assessment procedure

- *Notified bodies and National competent authorities*: enhanced cooperation + clearer role + Stricter criteria for designation
- *Vigilance and reporting of serious incidents*: harmonizing and improving the framework + HP and patient involvement
- *Coordination of NCAs in post-market assessment:* a platform for cooperation with stakeholders + Stronger coordinated alert system
- *Counterfeiting*: less regulated than for medicines yet it is no a lesser threat to patient safety

Improving coordination in the EU

- Two options
  - European Medicines Agency
  - Joint Research Centre
- Good practice :EMA - a workable and recognised model on patient involvement
- **How to adapt this model to medical devices sector**

Equitable access to medical devices

- Ensuring patients' equitable access to medical devices – not only "happy few"
- Important devices are no longer reimbursed as a result of budgetary restrictions.
- EU could play supporting role: exchange of best practices + HTA (European HTA network)

An opportunity to take concrete action to alleviate health inequalities

Conclusions and way forward

Patient involvement throughout the process will allow to harness patients' expertise for innovation, safety and quality of care .

Working together towards a stronger framework, to improve the safety of patients, build higher trust and confidence in innovative medical devices, and ultimately improve patients' health outcomes.

Thank You!

europeanpatients'forum

www.eu-patient.eu

info@eu-patient.eu