PATIENT INVOLVEMENT IN DECISION MAKING: A STRATEGIC IMPERATIVE FOR ALL STAKEHOLDERS

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VHCL LECTURE

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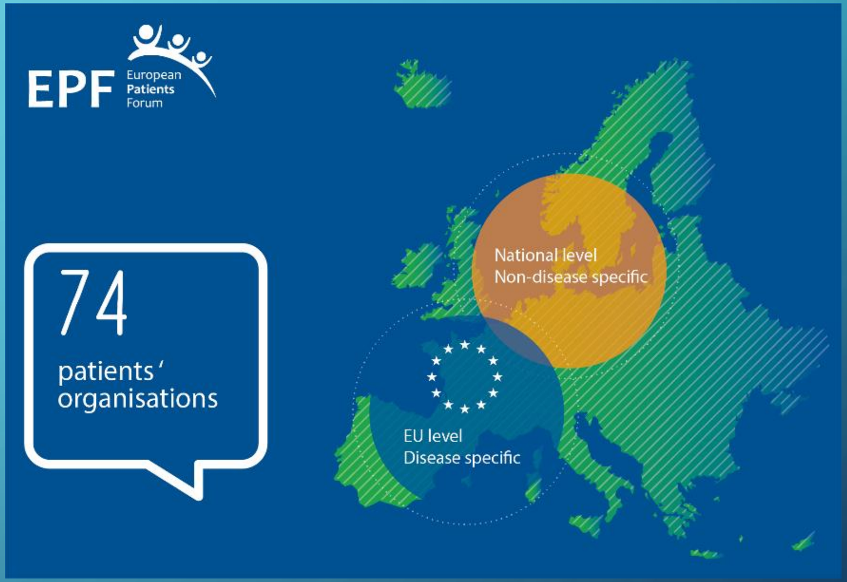
Presentation

- A little about me
- Introduction to the European Patients Forum
- Status of patient organisations – and added value
- Impact of patient leadership at EU level
  - Policy, regulatory, research
- Impact of patient leadership at national level
- Patients as conveners in policy environments
  - Patient Access Partnership, #Data Saves Lives, EU4Health
- Capability and capacity building
  - Examples from EPF
- Some personal learnings

About EPF

- European Patients' Forum
  - Independent & non-governmental
  - Umbrella organisation
  - Active since 2003
  - EU patients' voice
- Members
  - 74 patients' groups
  - EU disease specific organisations & National patient coalitions



Mission and vision

Vision!

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

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.”

The Added Value of Patient Organisations – a survey and publication

280 respondents : Policy & Advocacy

- 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 more **nuanced and balanced policy-making, based on fairness and equity**

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%).

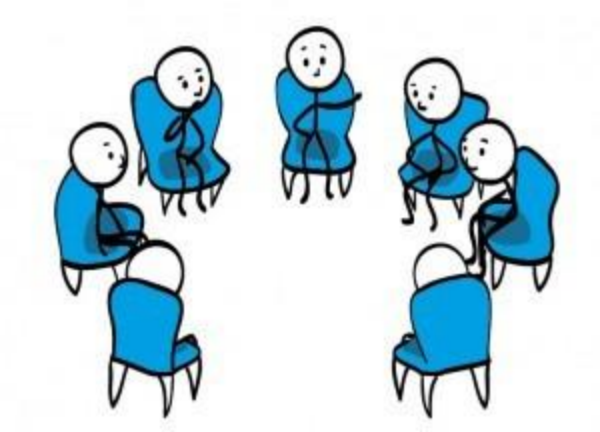
Huge discrepancies reported by POs

Inequities in the patients' voice

- The European environment – 'Brussels' – openness to the patients' voice
- Generally, in Western Europe, culture of patient **and** citizens' involvement more advanced, and thus recognised and resourced
- CEE – political backdrop often reflects the status and influence of patient organisations
- But, profound complexities and challenges can sometimes fast-track solutions – Bulgaria, Lithuania

Some challenges

- Lack of, and unpredictability of resources & funding, lack of unrestricted funding
- Credibility & alleged lack of independence
- Professionalisation vs. representativeness
- Emergence of new ‘on-line patient communities’
- Overcoming the culture of tokenism, cronyism
- Lack of performance measurement – or rather lack of knowledge on how to measure the impact of patient organisations?



Some drivers

- **Leadership**
- Strategic, anticipatory approach
- **Collaboration with other patient groups and other communities**
  - Solidarity
  - Shared learning
  - Effective use of resources

- **Structured Capacity –building**
- Alliances with the broader health stakeholder community
- **Explicit commitment to transparency**

PATIENTS' INCREASING ROLE

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

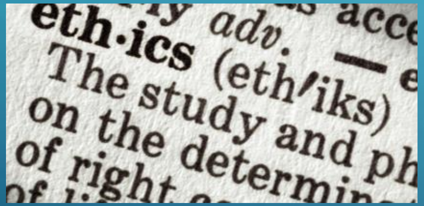
EUPATI
European Patients' Academy
on Therapeutic Innovation

Public perception

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
BfArM
MHRA
swissmedic

Competent authorities

Policy makers



Research ethics committees

HTA agencies and committees

- Driving force
- Co-researcher
- Reviewer
- Advisor
- Info provider
- Research subject

Clinical research

PATIENT INVOLVEMENT IN HEALTH POLICY

Pharmacovigilance Directive

(Direct Patient Reporting of Adverse Events)

Collaborating with Community Pharmacists

PATIENT INVOLVEMENT IN HEALTH POLICY

Clinical Trials Regulation

- *Informed consent*
- *Transparency*

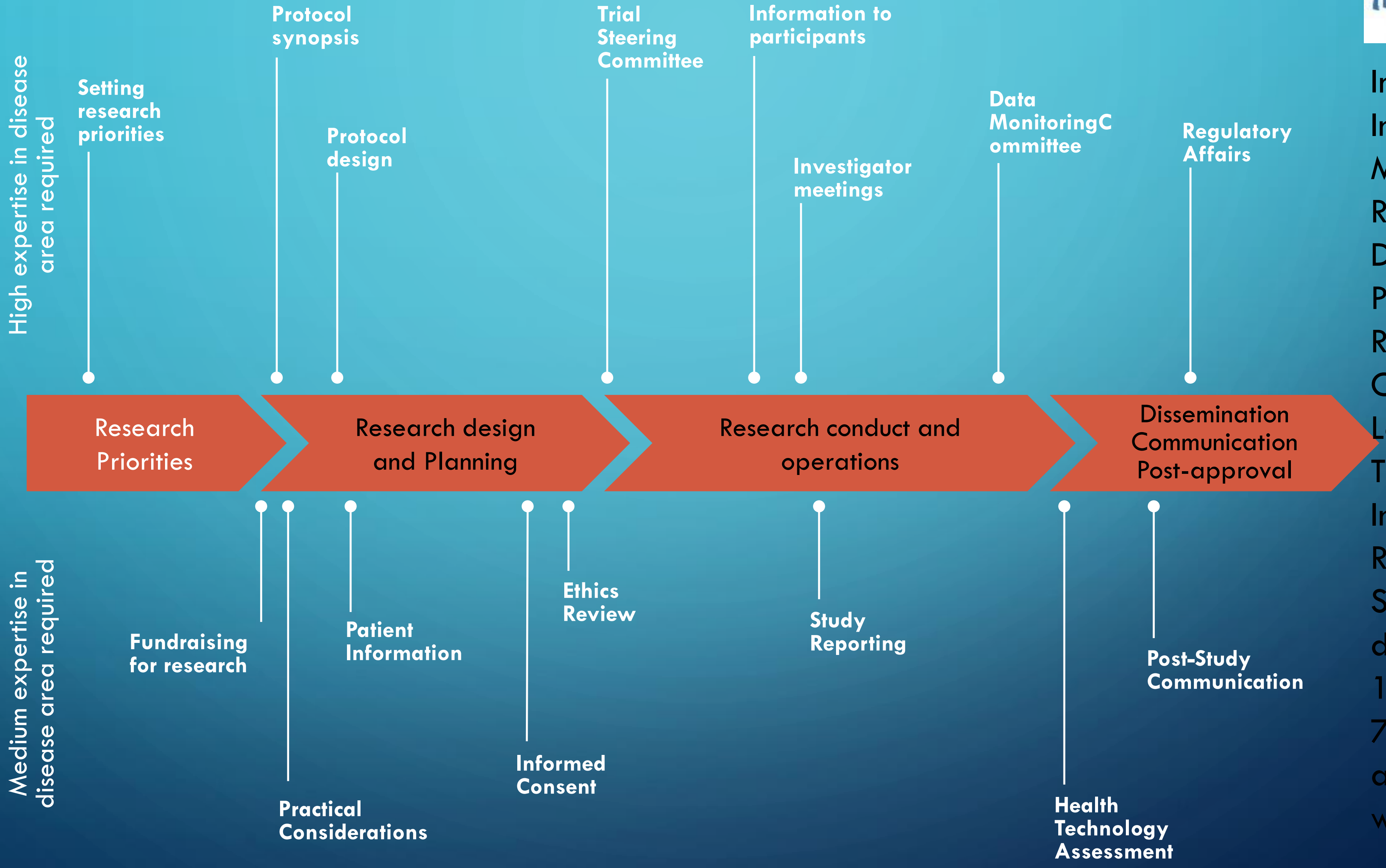
Collaboration with ‘ AllTrials’

PATIENT INVOLVEMENT IN HEALTH POLICY

Exchange of expertise, know how, leap-frogging, 'soft policy'

- *patient safety,*
- *quality of care,*
- *digital health,*
- *patient empowerment,*
- *patient access, etc*

PATIENT INVOLVEMENT IN MEDICINES R&D



High expertise in disease area required

Setting research priorities

Protocol synopsis

Protocol design

Trial Steering Committee

Information to participants

Investigator meetings

Data MonitoringC ommittee

Regulatory Affairs

Research Priorities

Research design and Planning

Research conduct and operations

Dissemination Communication Post-approval

Medium expertise in disease area required

Fundraising for research

Practical Considerations

Patient Information

Informed Consent

Ethics Review

Study Reporting

Health Technology Assessment

Post-Study Communication

Improving Patient Involvement in Medicines Research and Development: A Practical Roadmap. Geissler, Ryll, Leto, Uhlenhopp, Therapeutic Innovation & Regulatory Science (2017), doi: 10.1177/2168479017706405, and at www.eupati.eu

EUROPEAN PATIENTS' ACADEMY (EUPATI) – A GAME CHANGER

- Launched Feb 2012 as a Public Private Partnership,
- Funded by the Innovative Medicines Initiative coordinated by the European Patients' Forum .
- Builds competencies & expert capacity
- Reliable knowledge and materials on medicines R&D
  - EUPATI Toolbox in 12 languages, >2 million users from 217 countries
  - EUPATI Patient Expert Training Course (58 disease areas, 31 European countries, course 3 complete)
  - National Platforms in 18 European countries

EUPATI
European Patients' Academy
on Therapeutic Innovation

See http://www.eupati.eu

PARADIGM -PATIENT ENGAGEMENT

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

- **builds on EUPATI**'s guidance documents and processes

- provides a **framework** that will enable structured, effective, meaningful, ethical, innovative, and sustainable patient engagement and demonstrates the 'return on the engagement'

- develops **processes and** a **set of metrics** to measure the impact of patient engagement

See http://www.imi-paradigm.eu

From policy to practice

PARADIGM

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

- Particular emphasis on vulnerable groups
  - People with Alzheimer’s – Alzheimer Europe
  - Children and Young People with Chronic Diseases – St Joan de Deu Hospital, Barcelona

Research and priority setting

Design of clinical trials

Focus areas

Early dialogues with regulators and HTA bodies

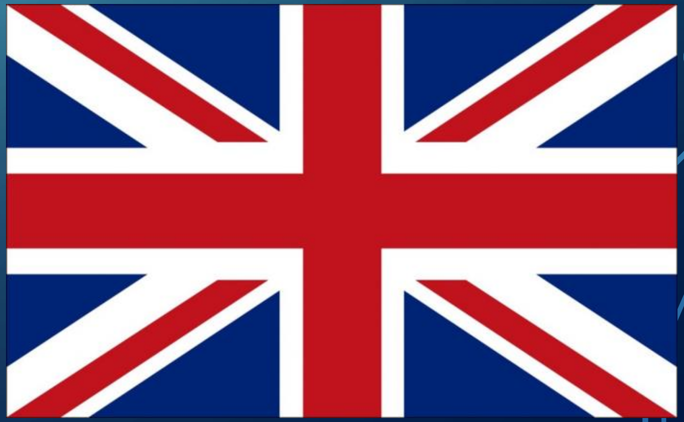
PATIENTS' INFLUENCE AT NATIONAL LEVEL
RECENT EXAMPLES

BULGARIA- NATIONAL PATIENTS COALITION

- White Paper on Personalised Medicines – A roadmap for integrating innovation in the 21st Century
- Consultation with members
- Dialogue with Government and other stakeholders
- Campaign on Vaccination
- Specific vulnerability of patients
- Collaboration with government to ensure vaccination policy works
- Patient organisation - agent of public health

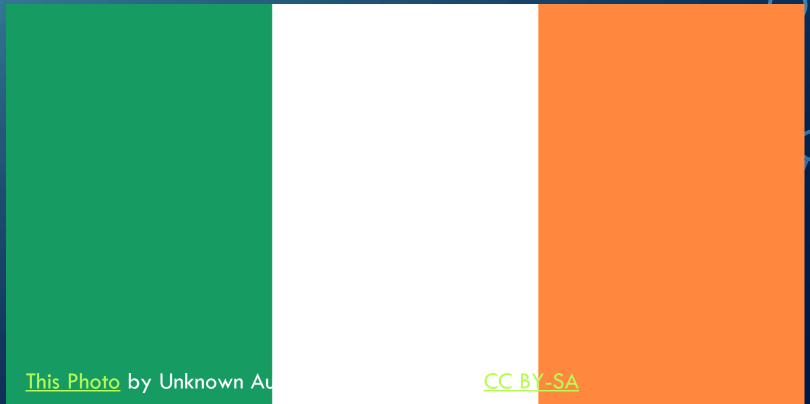
NATIONAL VOICES UK

- Letter to the Government on the implications of BREXIT on patients
  - Medicine shortages
  - Public Health crises know no borders
  - Lack of Health Care Professionals
  - Exclusion from EU Research cooperation
- Structured debate with government, academia and other stakeholders on the positive impact of “social prescribing” from a human and economic perspective



IRELAND

- IPPOSI – Irish Platform for Patient Organisations, Science and Industry Government
- Member of the national HTA agency scientific advisory board
- Charter on Medicines Assessment and Reimbursement
- National strategy for Patient Registries in Ireland
- Citizens ‘ Jury Initiative on Patient Data
- Member of Ireland eHealth Committee



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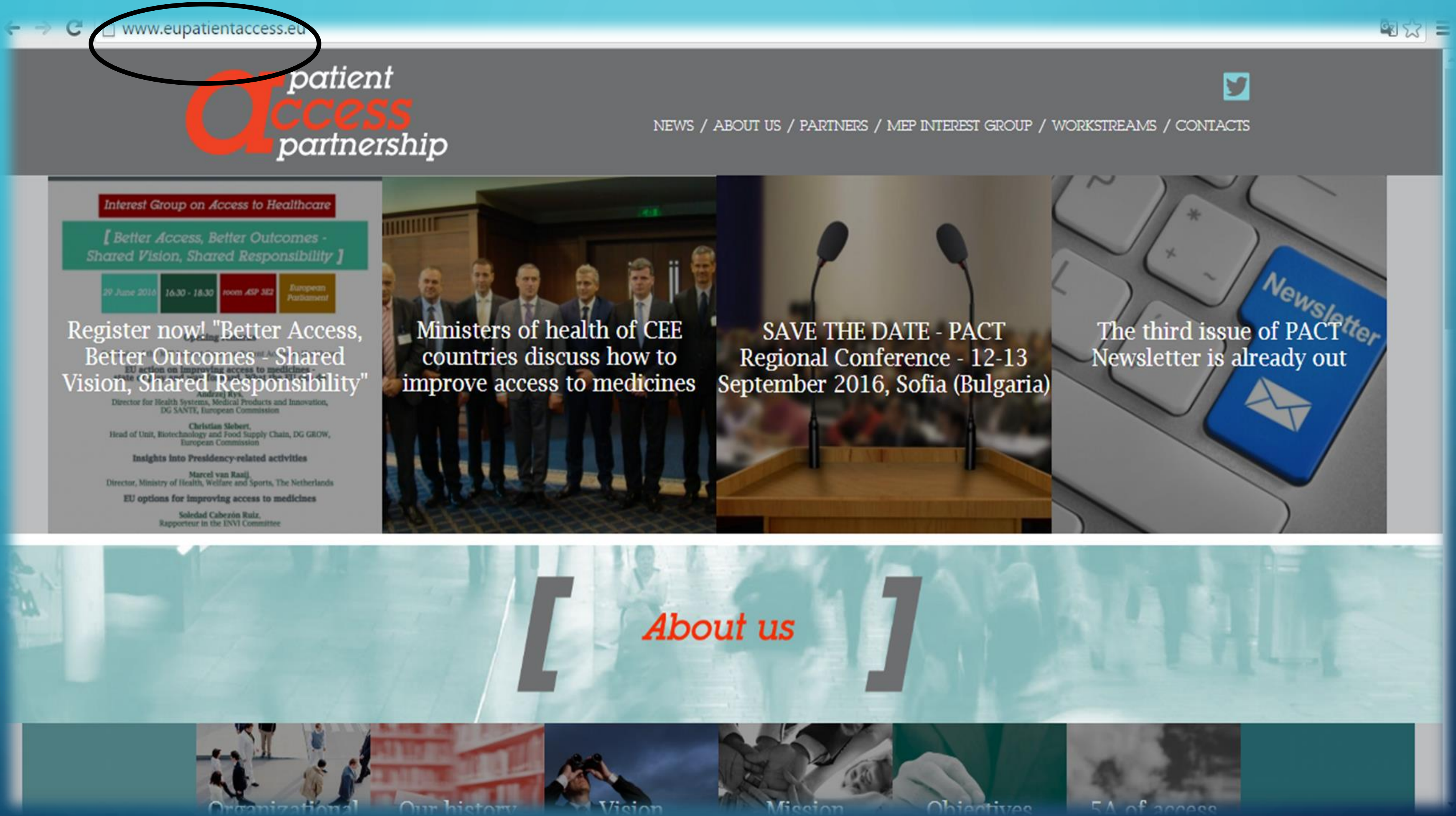
PORTUGAL

- Patient Centred Round Table on accessible Healthcare in Portugal
- Regional meeting of patients groups, authorities and NCP on the implementation of the Cross Border Healthcare Directive

- In Feb 2019 Portuguese National Health Council – an advisory body to the Ministry of Health – held its first seminar on “Public Participation: The Experience of National Health Councils”,
- A Charter for Public Participation in Health, a collaborative initiative led by a group of Portuguese patient and user organisations, was discussed at the national parliament with two parliamentary groups.

PATIENTS AS CONVENERS



Register now! "Better Access, Better Outcomes - Shared Vision, Shared Responsibility"

Ministers of health of CEE countries discuss how to improve access to medicines

SAVE THE DATE - PACT Regional Conference - 12-13 September 2016, Sofia (Bulgaria)

The third issue of PACT Newsletter is already out

Data Saves Lives

Vision and Mission

➢ Vision

“A Europe where trustworthy data sharing supports health and scientific research to meet the needs of patients and address the challenges faced by our healthcare systems”

➢ Mission

“To create a European Health Data Portal that will build awareness and understanding on:

- ✓ why data is important;
- ✓ how it is used, and
- ✓ provide a trusted environment for dialogue about the use of health data in Europe”

Future of health cooperation

EU: DO MORE FOR HEALTH!

Health is absolutely and unequivocally a core business of the EU

What are we asking for?

We call on the European Commission to step up coordinated EU action to tackle cross-border health challenges.

SIGN THE PETITION

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Supporting Organisations

EU4health

THE VALUE OF CAPACITY BUILDING – EXAMPLES FROM EPF

Training for Young Patient Advocates

In July, the third EPF Summer Training Course took place in Vienna on overcoming discrimination -

- **39** participants from **23** European countries gathered for the three-day-training
- More than **20** different chronic conditions were represented
- Age ranged between **18** and **31**, approximately **60%-40%** (female-male), majority of participants were patients themselves
- **38** participants engaged in the online follow-up post-event activities

Education and Training

Annual EPF Capacity Building Programme on Empowering Leadership and Positive Organisational Governance

First face-to-face module
Brussels, March

Intensive online coaching

Second face-to-face module
Warsaw, September

Some learnings

- The importance of solidarity, community, identity – avoidance of competition and ‘ disease- ranking’, and thus ‘ divide and rule’
- Clarity of purpose – strategic thinking and planning
- Evidence-based advocacy with an end goal in mind
- Using policy hooks – eg Sustainable Development Goals - Universal Health Coverage
- Patients in the centre – natural ‘ convener’ to bring different stakeholders together for solution oriented discussions BUT
- POs should not become ‘ institutionalised’ or comfortable , but powerful change agents
- Advocacy – then implementation- full circle approach is key

Some learnings

- Integrity, independence, transparency and credibility – with all partners – not only PHARMA
- Ownership of the narrative and terminology –words matter !
- Economic arguments alongside the human factor – a powerful blend
- Capacity building akin to continuous professional development – a one off event will not do it
- Good practice exchange , replication , scale up – how to systemise this
- Learning, monitoring and evaluation – and application
- Patient involvement in health systems' design and health systems' strengthening – much to be learned from pI in the life cycle of medicines
- The value of Public Private Partnerships
- Trend towards pharma/technology/ digital/ data -new partnerships – POs – be ahead of the curve

THANK YOU !