Uptake of innovation – policy and practice: current status and stumbling blocks
Patient perspective: did we progress on patient access?

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February 2011 LSE

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…is the umbrella organization of 37 national MS-Societies in currently 34 European countries and represents more than half a million people affected by MS and their caregivers.

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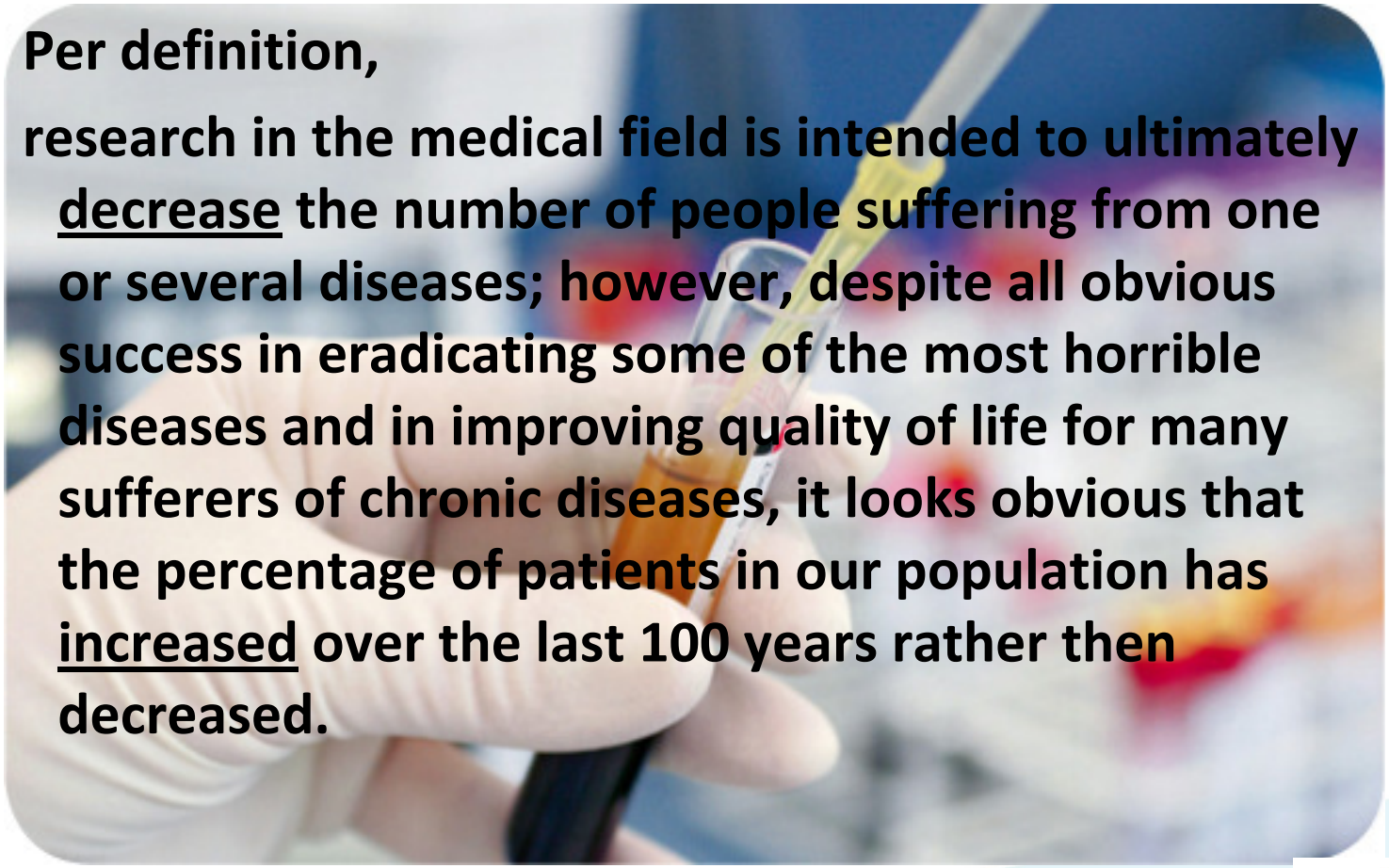
Setting the scene – the paradox development of health technology



Per definition,

research in the medical field is intended to ultimately decrease the number of people suffering from one or several diseases; however, despite all obvious success in eradicating some of the most horrible diseases and in improving quality of life for many sufferers of chronic diseases, it looks obvious that the percentage of patients in our population has increased over the last 100 years rather then decreased.

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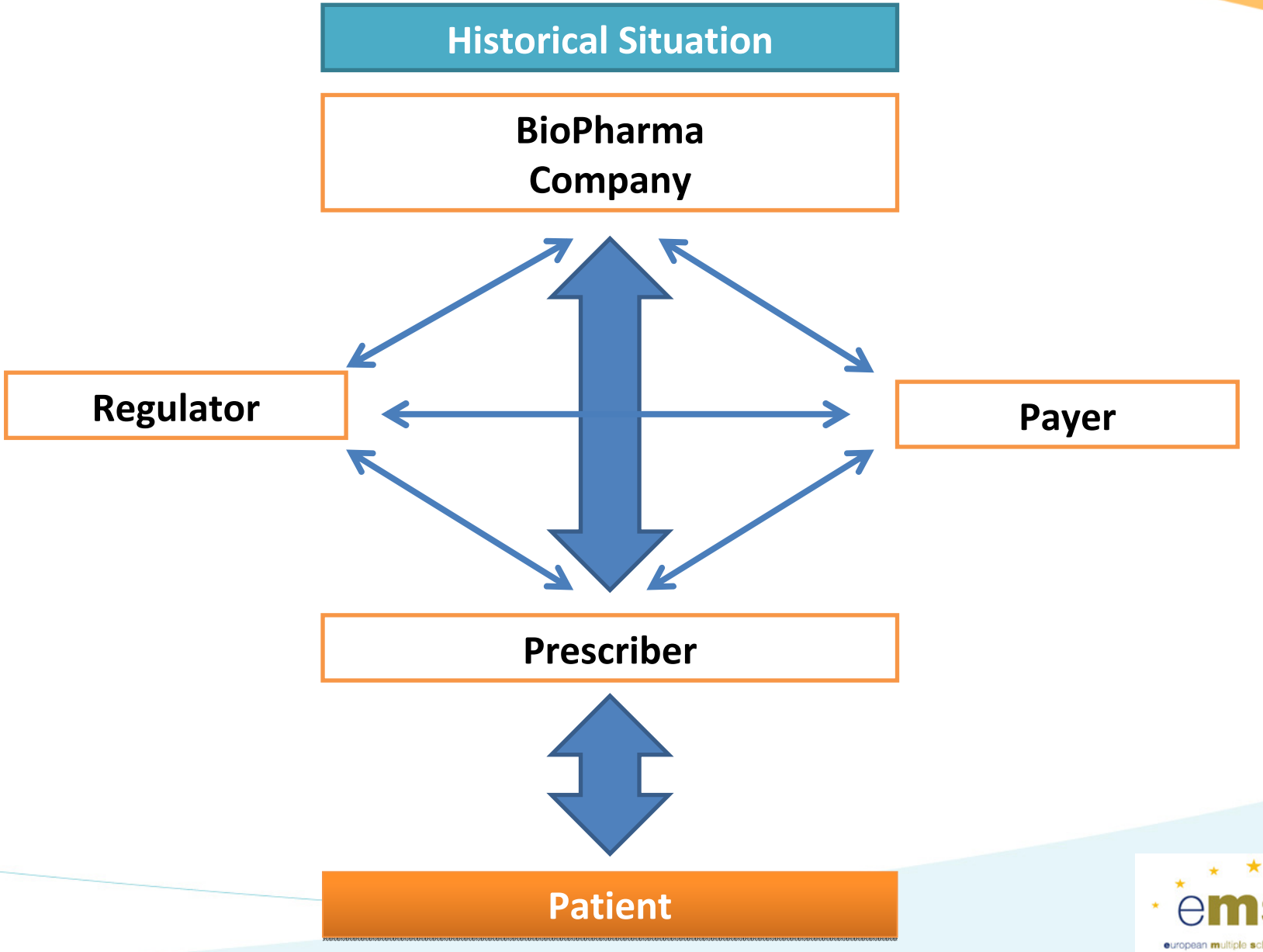
The position of the patient in healthcare transactions



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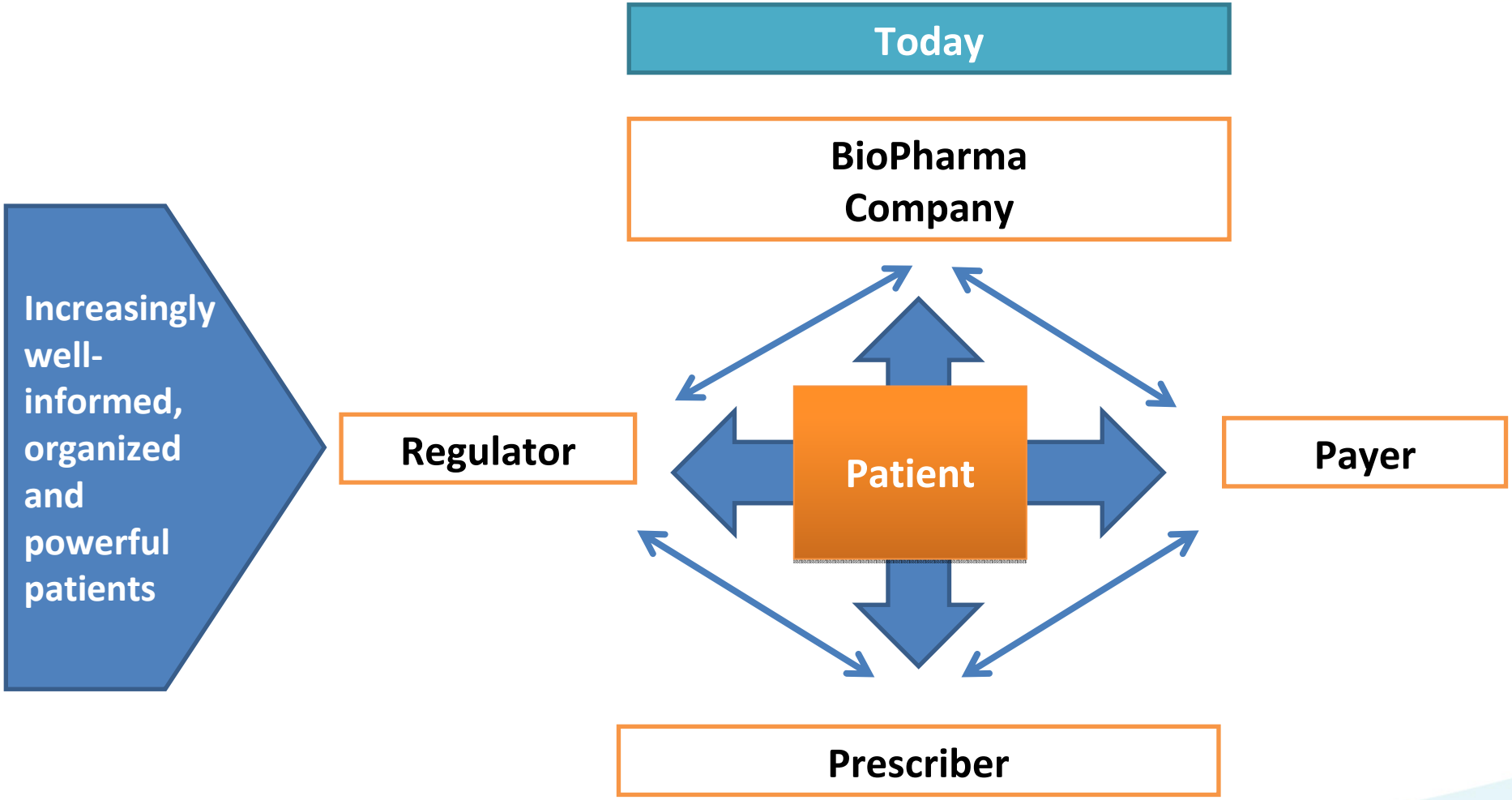
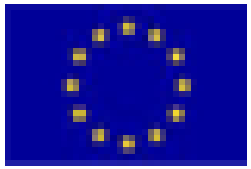


High Level Pharmaceutical Forum

Review on the implementation of the recommendations issued by the High Level Pharmaceutical Forum

Questionnaire for stakeholders members of the Pharmaceutical Forum



II.1 Access to medicines for EU citizens

a) Timely access and affordability

Q15. Have you taken concrete initiatives to improve timely access to valuable innovation and access to medicines for all citizens?

b) Ensure sustainable availability and delivery of medicines to all EU Member States, in particular to small markets

Q16. a) What initiatives have you taken to improve and ensure the sustainable availability and delivery of medicines in all Member States? What about the specific case of small markets?
b) Have you adopted measures designed to facilitate the **supply to small markets**?

c) Ensure equal access to orphan medicines

Q17. For marketing authorisation holders: have you established **early dialogue** with pricing and reimbursement authorities in order to discuss what clinical data could be required for later clinical value assessments and pricing and reimbursement decisions?

Q18. Have you undertaken initiatives to build EU-level **awareness and expertise on orphan diseases** (e.g. establishment of standardised patient registers at international level, networks of centres of expertise)?

II.2 Continued momentum on pricing and reimbursement

Q19. Are there any Pharmaceutical Forum recommendations on pricing and reimbursement that you have not yet implemented (or fully implemented) and which would require further work from your side? Which actions do you foresee in the future?

The European Medicines Agency network

- A unique structure
- The Agency partners with:
  - More than 40 national competent authorities
  - 4000 EU Experts
  - European Parliament
  - European Commission
  - Establishes relation with non-EU regulatory authorities, international health organisations, industry academia, and the general public

Patient involvement in the Agency's activities: so-far experience (1)

Full members of:

- Management Board
- Committee for Orphan Medicinal Products (COMP)
- Paediatric Committee (PDCO)
- Committee for Advance Therapies (CAT)

Patient involvement in the Agency's activities: so-far experience (2)

- Patients and Consumers Working Party (PCWP)
- Review of Product Information:
  - EPAR summaries, Package Leaflets, safety information–Q&A
- CHMP (Ad-hoc collaboration):
  - Input on assessment of products (e.g. thalidomide, tysabri, etc)
  - Experts in scientific advice/protocol assistance
  - Input in guideline preparation
  - Observers in Pharmacovigilance working party (pilot phase)
- Regular participation in Agency's workshops & conferences

Which is the added value of involving patients in the scientific process?

In general, patients bring real-life experience of the disease and its current therapeutic environment; as a consequence:

- it enriches regulatory outcome by complementing it with the views of those directly affected by regulatory decisions,
- it increases confidence and trust in the regulatory process
- it incurs in higher level of transparency

EMA Scientific Committees Working Party with Patients' and Consumers' Organisations (PCWP)

PCWP Members: 15/25 Eligible Organisations + representatives from Agency's Scientific Committees (CHMP, COMP, HMPC, PDCO and CAT)

Co-Chair: EMA / Patient/ Consumer Rep

4 meetings per year (one joint with Healthcare professionals)

Selection criteria for involvement of patients' organisations

- Legitimacy
- Mission/ objectives
- Activities
- Representativity
- Structure
- Accountability and Consultation Modalities
- Transparency

MS Barometer 2009 -
monitoring accessibility & resources for PwMS

- 7 areas were covered:
  - Section 1: Access to treatment & therapies (19 questions)
  - Section 2: Research (3 questions)
  - Section 3: Employment (8 questions)
  - Section 4: Empowerment (7 questions)
  - Section 5: Reimbursement of Costs (6 questions)
  - Section 6: Data Collection (5 questions)
  - Section 7: Medication coming to the market (3 questions)
- 29 countries participated
- Vast inequalities in existence of and access to health care transactions confirmed (2nd time)

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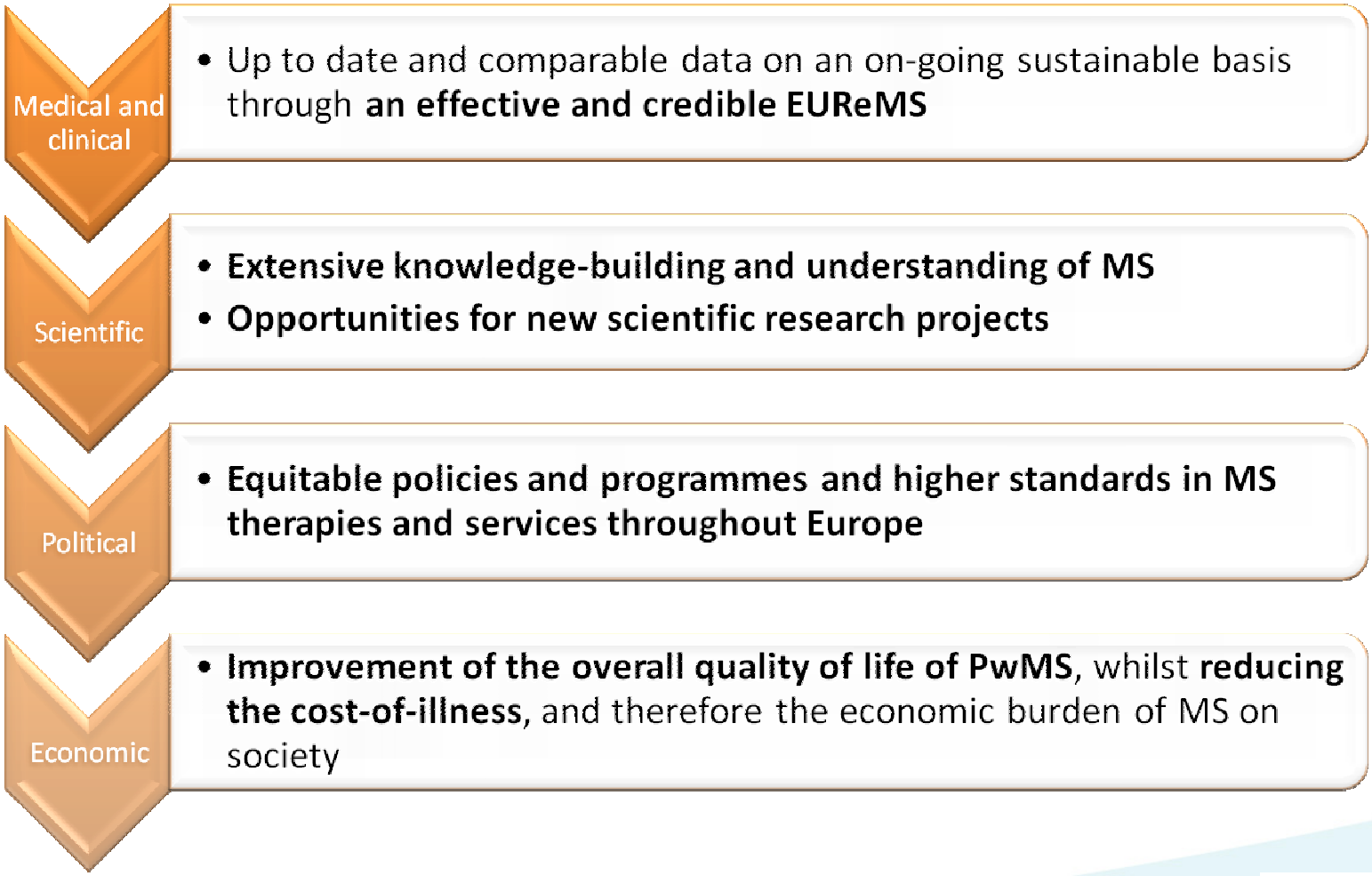
European Register for Multiple Sclerosis



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CONCLUSIONS

- **Many good examples exist <u>on EU level</u> for improved accessibility for patients to health care policy development and implementation**

BUT

- **<u>Considerable room for improvement</u> when it comes to the question if and how to include patients in a shared responsibility in health care transactions on <u>Member State level</u> (HTA, direct reporting in pharmaco-vigilance, national budget prioritisation)**

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CONCLUSIONS

- Improved, but still very unsatisfactory access to therapies and care in many EU Member States
- Huge variations in drug access between Member States and between diseases
- Variations even within one country on regional level !
- Lack of funds is not the main limiting factor, but lack of prioritization of health care budgets!
- Only healthy citizens can and will contribute to GDP (relation health care & societal costs!)

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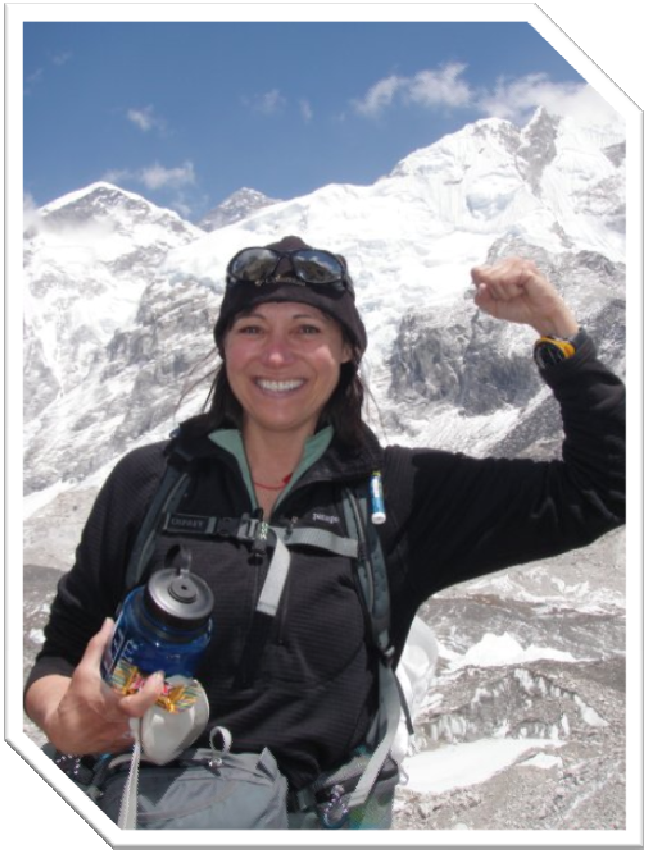
Thank for your attention



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