



13.9.2012, Madrid

XII ENCUESTRO DE LA INDUSTRIA FARMACÉUTICA ESPAÑOLA

The importance of efficacy assessment for the research-based pharmaceutical industry

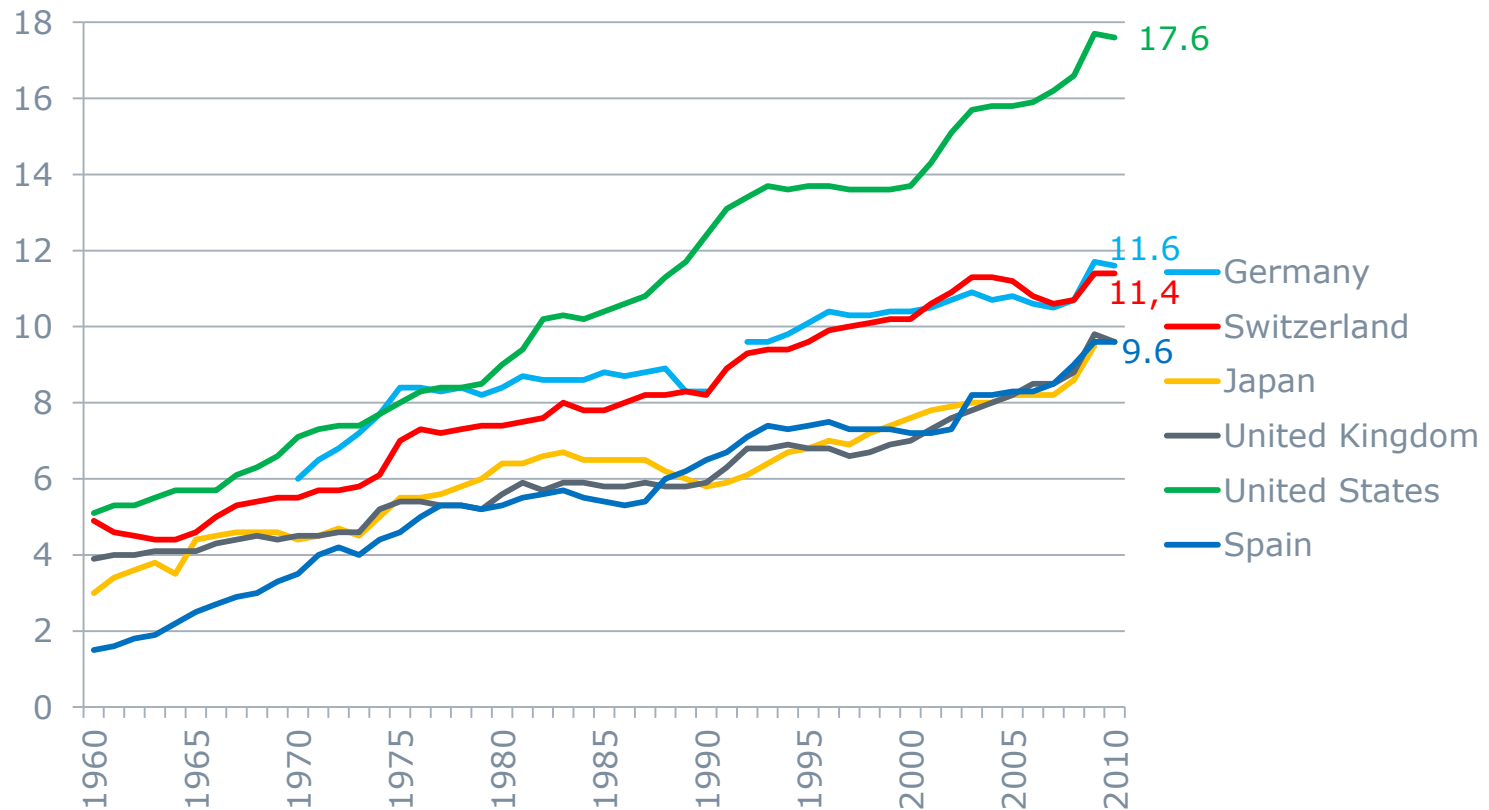
Thomas B. Cueni, Secretary General, Interpharma

Today's main challenges for the industry

- Policy makers becoming increasingly concerned about **health expenditure and cost of innovation**
- Debate too **much focused on cost and not on efficiency**
- Growing concern over possible ineffective (or harmful) **use of untested technology**
- Need for **enlightened tools for assessing value of health care services**


Rising health care expenditure

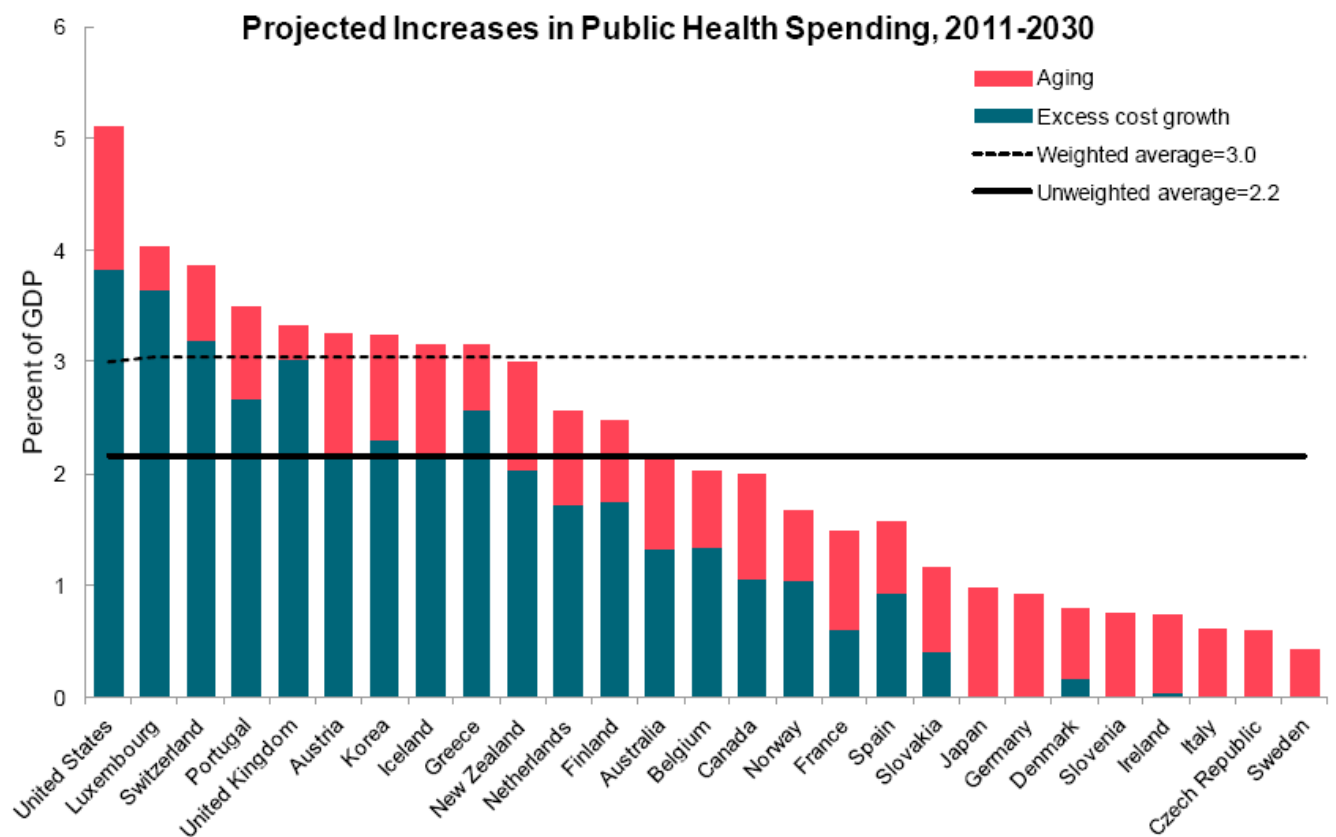
Health care expenditure as a percentage of GDP



Source: OECD health data 2012.

Public spending pressures in advanced countries are substantial and varies

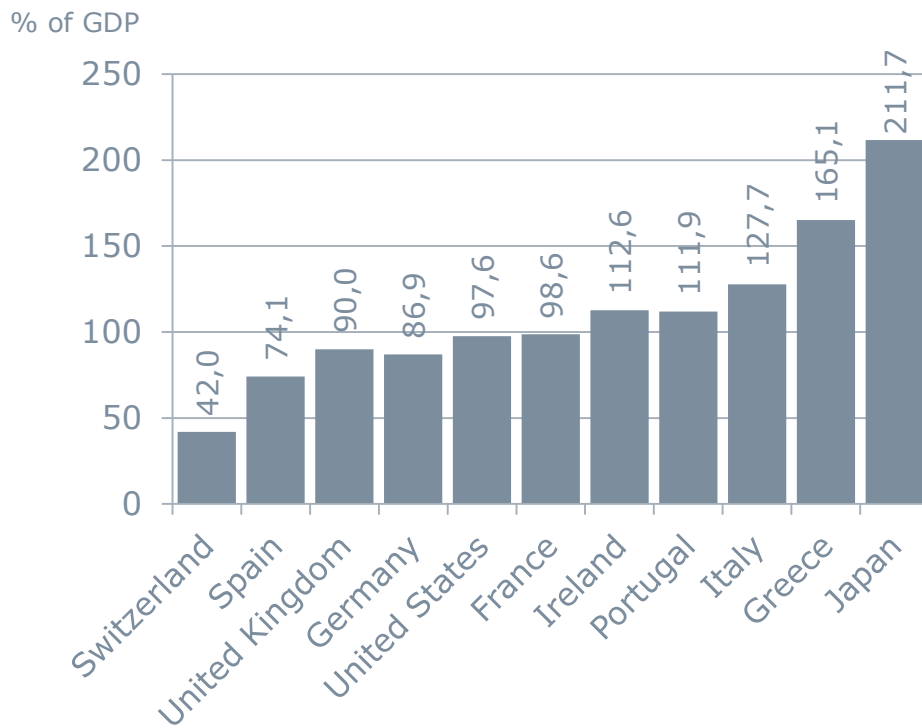
 "(...) rising spending on health care is the main risk to fiscal sustainability."



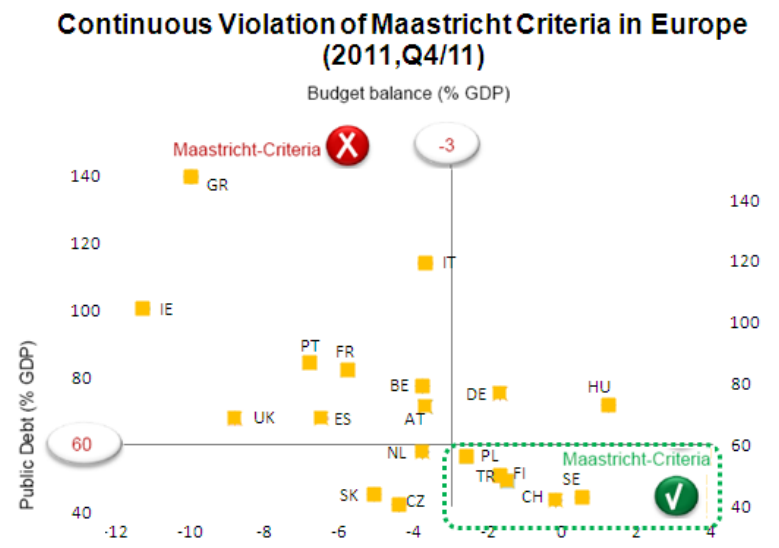
Source: Global Trends in Public Health Spending and the Outlook , International Monetary Fund (IMF), 2011.

High debt and fiscal deficits in several EU countries are driving healthcare reform

Maastricht definition of general government gross public debt, As a percentage of nominal GDP



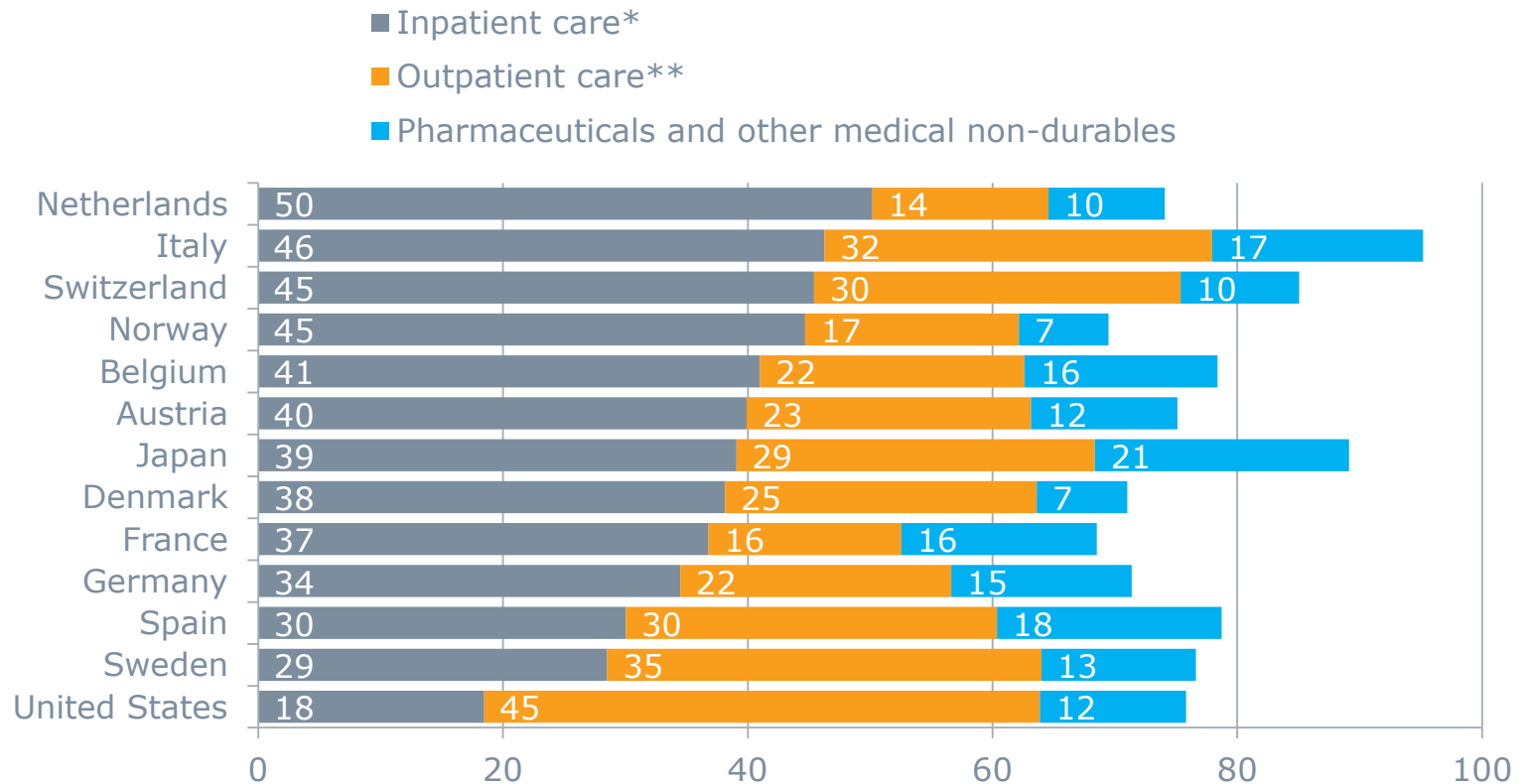
Government financial balances 2011, net borrowing (+), net lending (-), % of nominal GDP



Source: OECD Economic Outlook 90 database, 2011, Source: Region Europe Pharma, Global Insight 2011, Deutsche Bank 2011.

Where to put the focus?

Health care spending by component, 2010 (or most recent year)



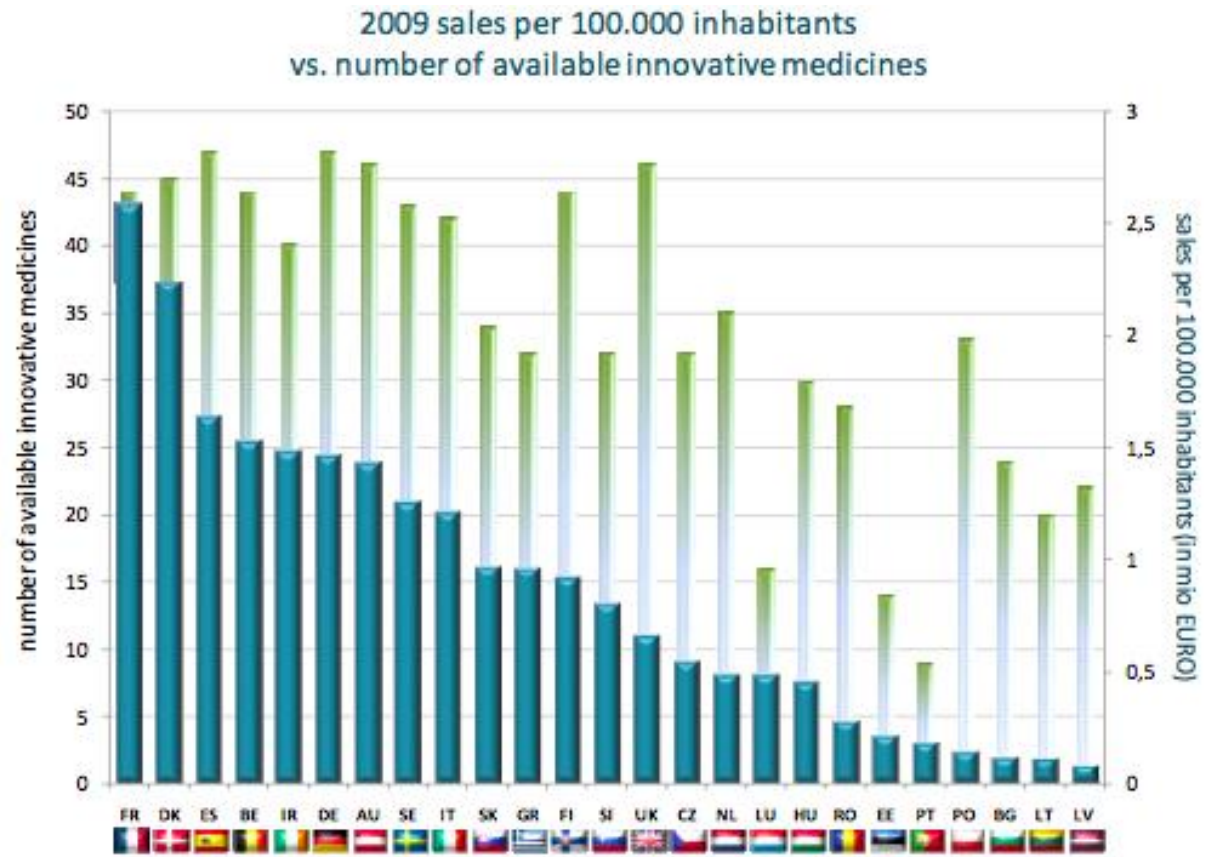
* Refers to curative-rehabilitative care in inpatient settings

** Excludes home-care and ancillary services

Source: OECD Health data 2012

The importance of efficacy assessment for the research-based pharmaceutical industry

Inequalities in availability of and access to innovation



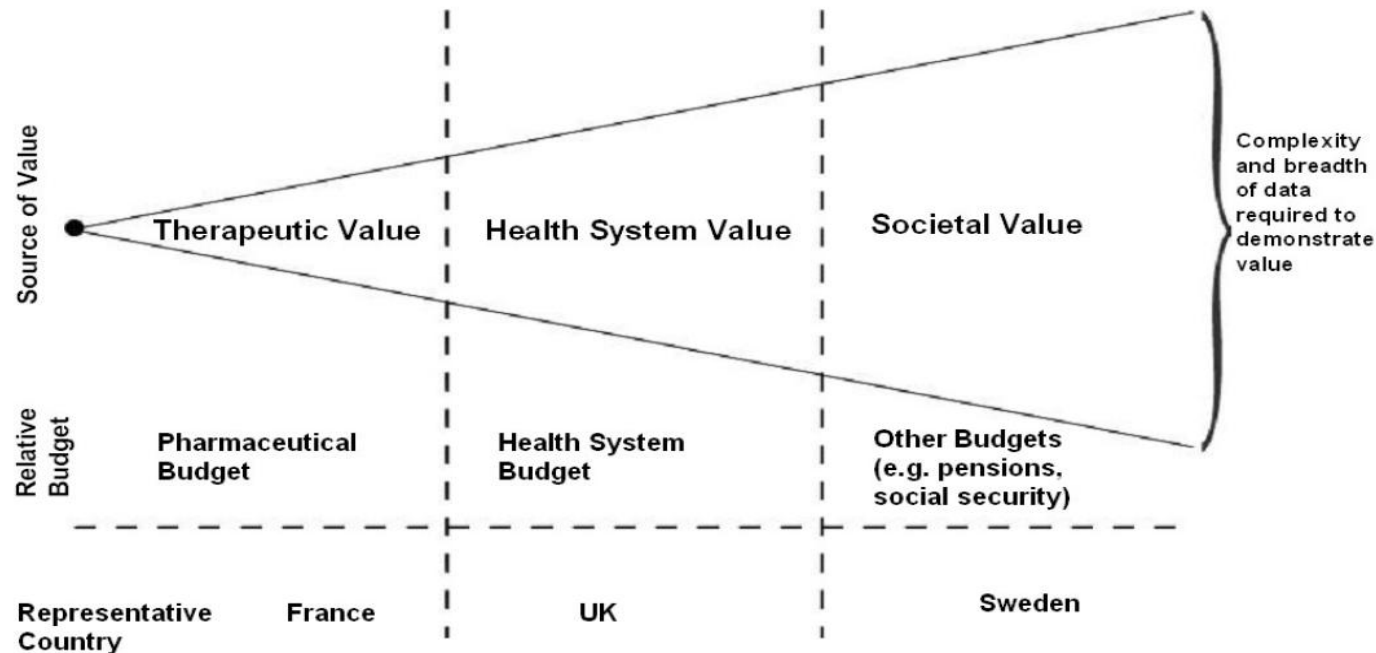
Source: Innovation and Solidarity in Pharmaceuticals. EU Belgian Presidency Ministerial Conference, 09/2010.

Availability vs affordability

- Huge variation in availability and uptake of medicines across European countries
- Variations do not appear to be linked to differences in availability of medicines across markets but to differences in the average GDP per capita
- Availability of medicines in smaller markets highly influenced by regulatory requirements in addition to financial constraints or affordability considerations

What is the value of innovation?

Spectrum of Value (Payers) – Broad Sources and Perspective of HTAs



How to put a value to a new medicine?

1. Competitive market price

2. Therapeutic comparison (=value based pricing)

- Clinical relevance (added therapeutic value): Lower mortality, faster cure, improved quality of life, better compliance, better outcomes
- Cost effectiveness: Faster re-integration, in-patient costs/out-patient costs, cost-benefit

3. Country baskets (=political value)

- Not higher than average of...
- The average of the three lowest...
- The lowest of any...

Motivation for Swiss Project on HTA

Growing pressure on social health insurance

- Demographic change
- Chronic diseases
- Insufficient quality and efficiency in fragmented health care

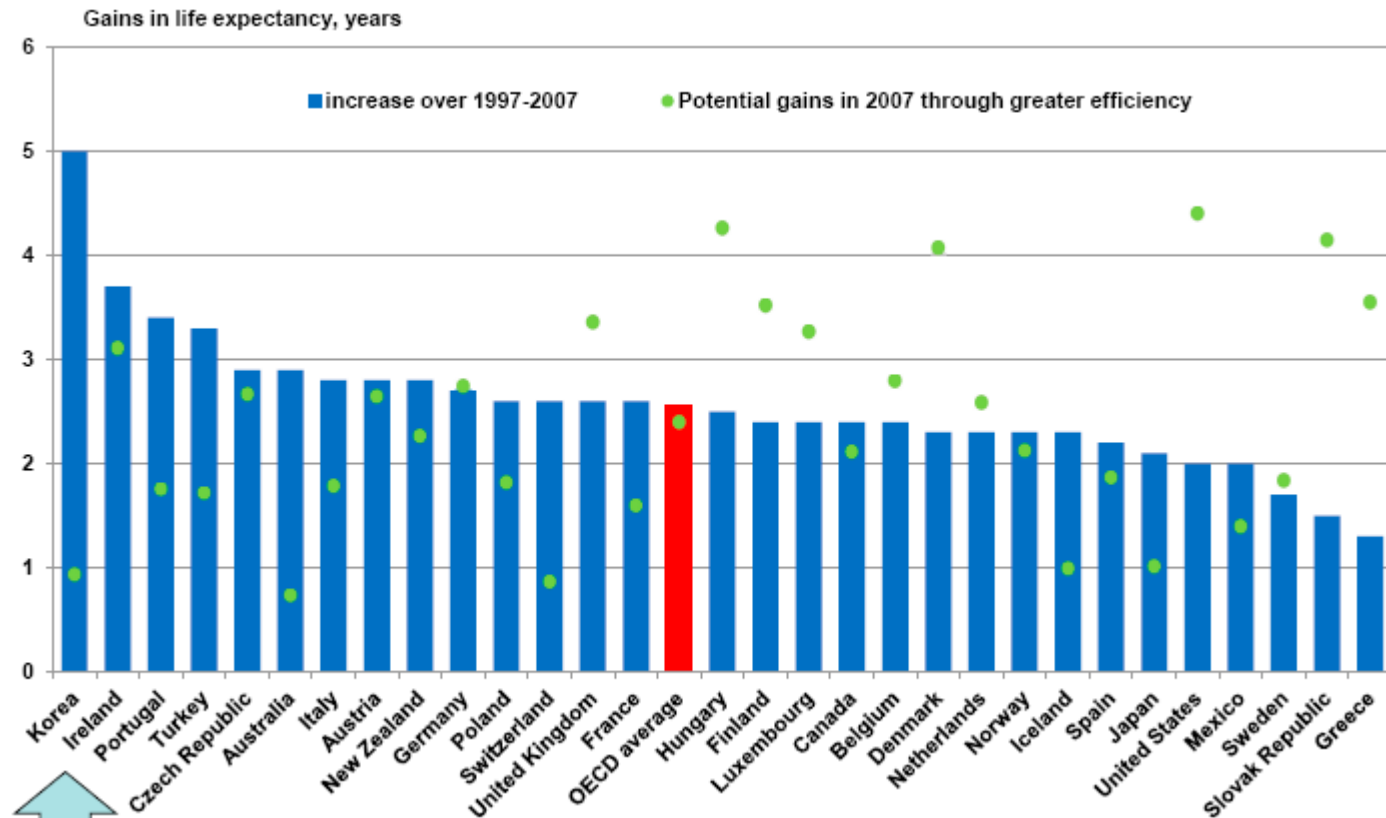
Need for

- Better value for money
- Sustainable financing of health insurance
- Alternatives to rationing
- Alternative to oversimplifying methods and fixed thresholds

Situation in Switzerland

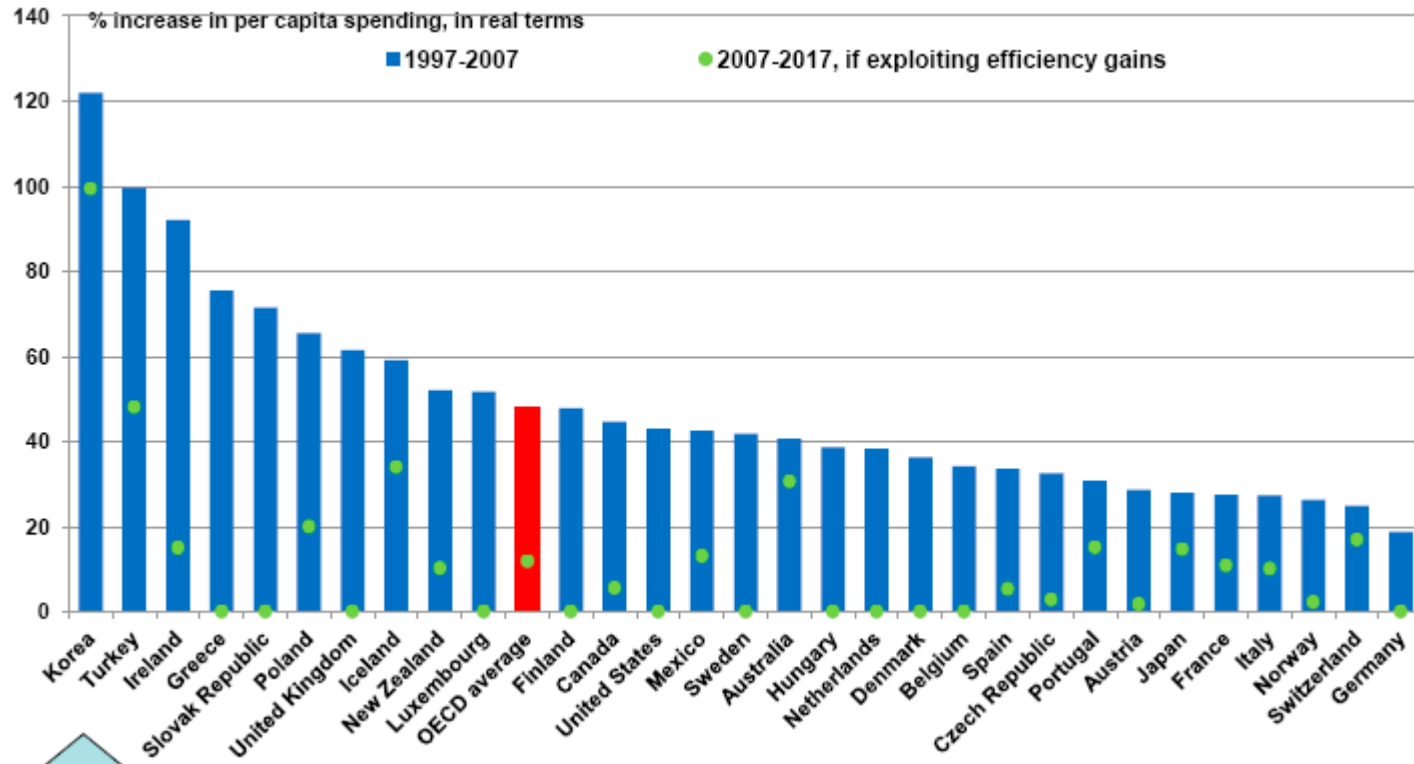
- Basic and fragmented use of HTA
- Political initiatives on federal and cantonal level to improve quality and cost-efficiency in health care
- Tradition of dialogue among stakeholders and pragmatism

Exploiting efficiency gains would allow to improve health outcomes further ...



Source: OECD Health Data 2009; OECD calculations.

...and help to contain future health care spending



Source: OECD Health Data 2009; OECD calculations.

SwissHTA - A Stakeholder Project

Initiated in 2010 by Interpharma and Helsana (sick fund)

- Based on a proposal by Prof. Michael Schlander

Aim of the project

- Develop a consensus on the development of HTA in Switzerland
- Broad stakeholder involvement and support for consensus

Project Partners of SwissHTA

- Santésuisse (association of Swiss sick funds)
- Interpharma (association of Swiss research based pharmaceutical companies)
- Federal Doctors Association of Switzerland (FMH)
- Swiss Academy of Medical Sciences (SAMS)
- Federal Office of Public Health (FOPH, as observer)
- Conference of Cantonal Health Ministries (as observer)



santésuisse

Die Schweizer Krankenversicherer
Les assureurs-maladie suisses
Gli assicuratori malattia svizzeri

interpharma^{ph}

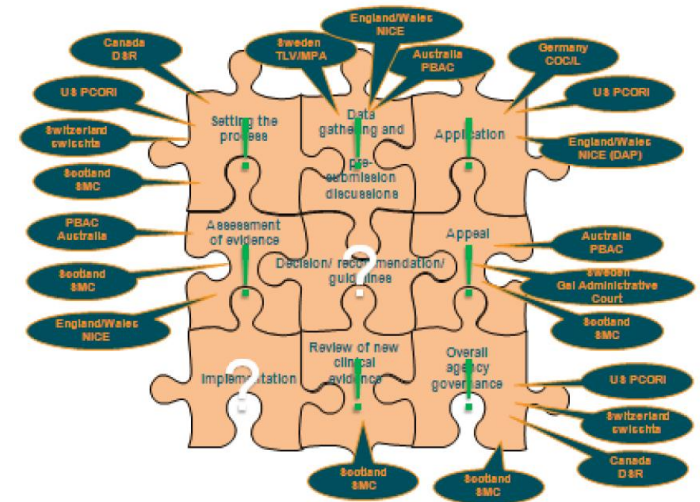


Verbindung der Schweizer Ärztinnen und Ärzte
Fédération des médecins suisses
Federazione dei medici svizzeri
Swiss Medical Association



Why an Industry Engagement?

- Switzerland is a latecomer in formal HTA
- A cantonal initiative (Medical Board) adopted a rather simplistic NICE-style rationing approach in pilot projects (2009)
- Interpharma wanted to
 - Proactively shape the HTA agenda based on EFPIA's HTA principles
 - Prevent
 - oversimplified methods
 - rationing
 - unrealizable rigid demand for evidence levels
 - Promote
 - differentiated value assessment
 - capturing value and cost from a broad societal perspective
 - pragmatic approach to evidence levels



“WZW-Criteria” in Swiss Health Insurance

Health Insurance Law

- For reimbursement all benefits must comply with WZW-criteria
- Regular reassessment

Wirksamkeit: Relative efficacy / relative effectiveness

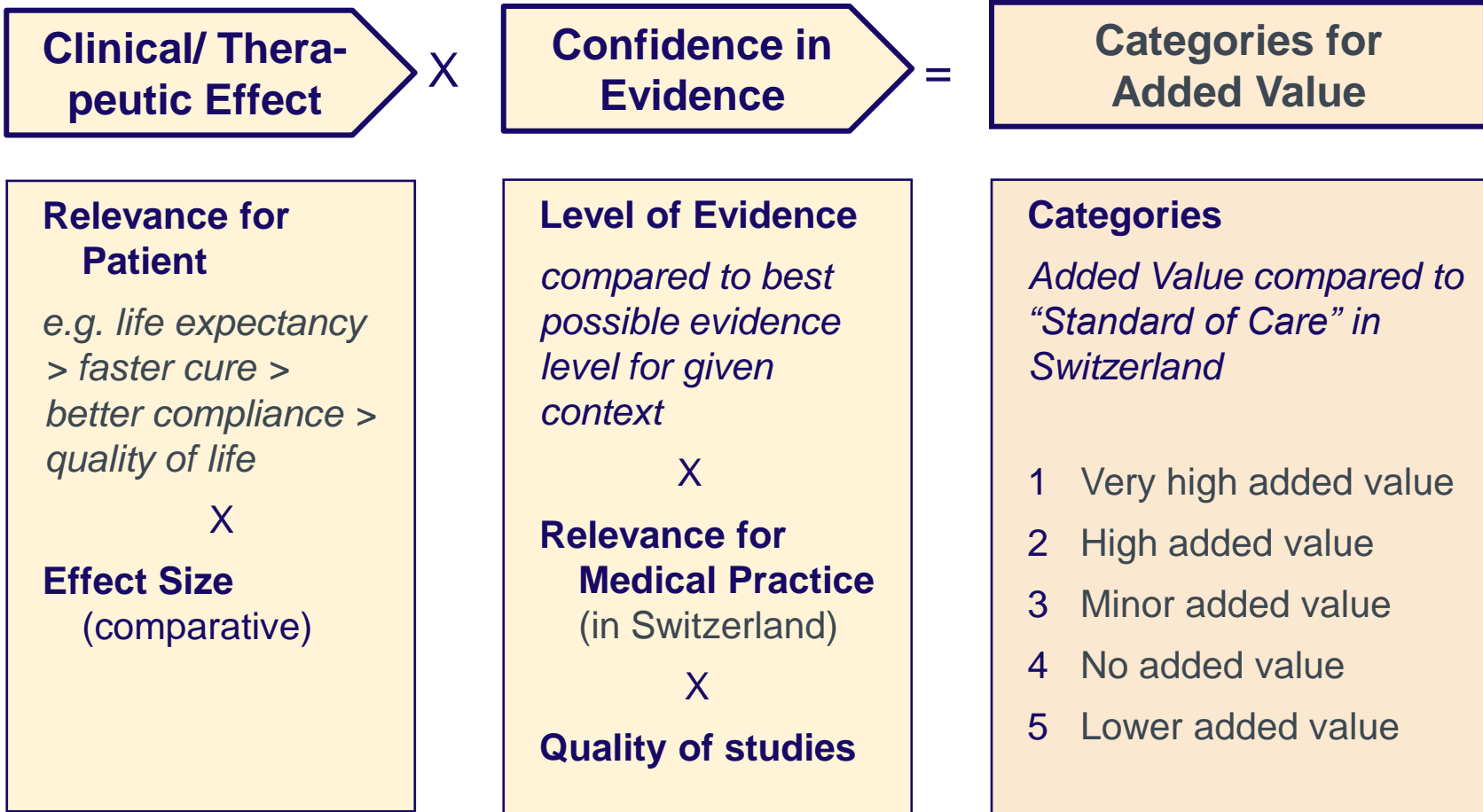
Zweckmässigkeit: Appropriateness for social health insurance

Wirtschaftlichkeit: Economics / Efficiency

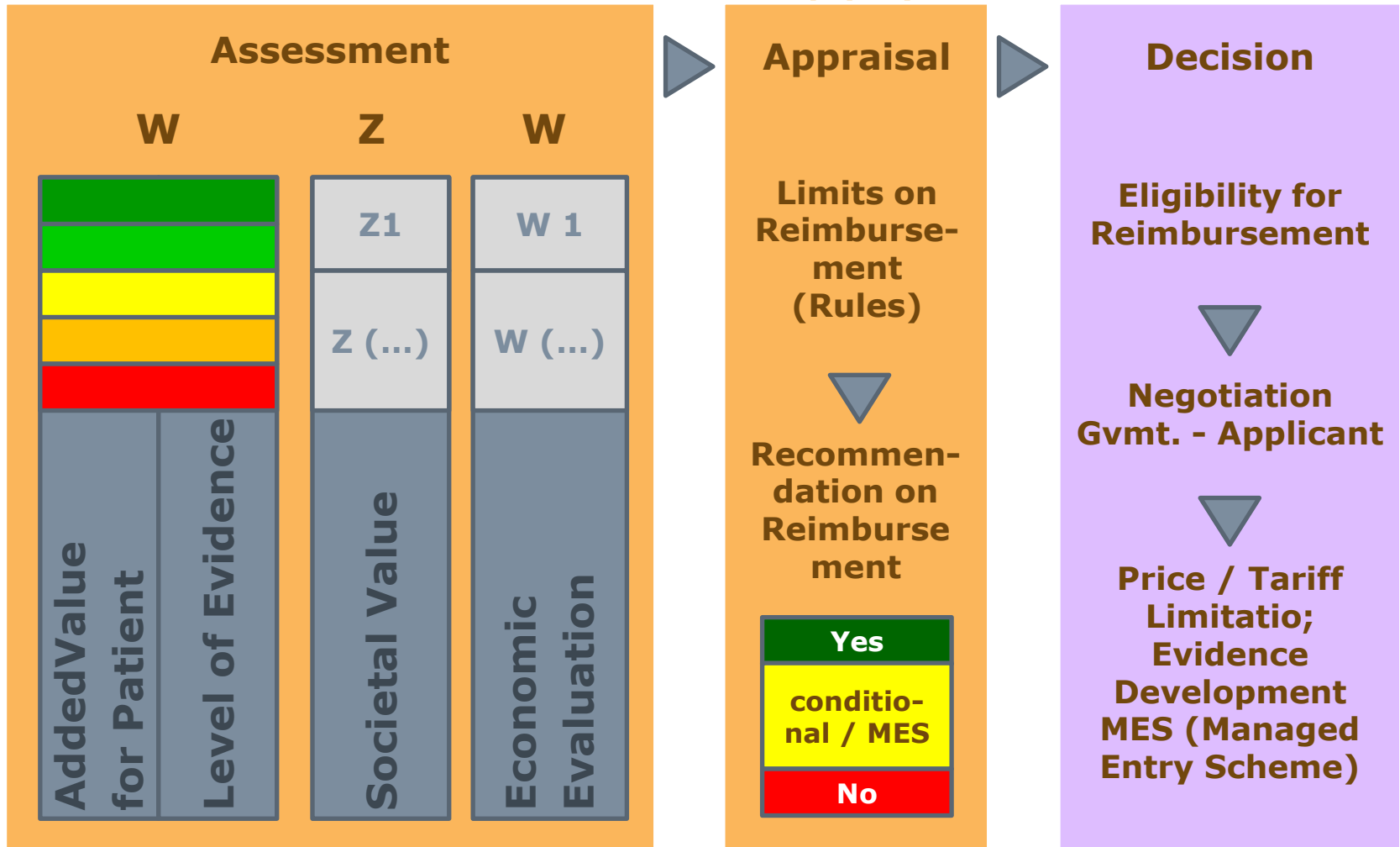
Current Practice

- WZW defined only in part and applied inconsistently, regular reassessment for drugs only
- Parliamentary Commission asked for remedy in 2009

Assessment of Efficacy/Effectiveness: Added value, individual (patient) perspective



SwissHTA – A frame to apply WZW-Criteria



Result of Consensus Process

Learning experience for all involved

- Open exchange of views (Chatham House Rule), tough discussions, constructive and productive dialogue

Consensus Paper

- Short Paper (30-pages, in German) finalized by Project Steering Group, October 19, 2011
 - Officially adopted by santésuisse, interpharma, FMH and SAMS, during November 2011
- Extended paper early 2012, with full scientific documentation

Continuing collaboration

- Members of SwissHTA renew engagement to support the Federal authorities in implementing and further developing SwissHTA



Some Key Elements of Consensus

- HTA as effective decision support for benefit management in social health insurance for **new and established products, procedures and services (all technologies)**
- **rHTA**: Rapid HTA process, primarily for new (single) technologies
- **cHTA**: Complete HTA process, primarily for existing technologies / (complex) clinical pathways
- Broad **stakeholder involvement throughout all stages of HTA process**
 - e.g. selection of topics, early consultation, scoping, assessments, appraisals, comments on recommendations, ...
- **Transparency** of evaluation processes, criteria, and methods; key documents and rationales underlying decisions
- **Implementation within existing legal framework**
 - Building on existing processes and methods

Documentation on www.swisshta.org

- Consensus paper
- Supplementary paper incl. extended slide set (in German only)
- Guiding Principles Paper
- International Workshop
 - Presentations: slides and videos (in English)

SWISSHTA **SwissHTA Consensus Project**

VALUE & VALUATION OF HEALTH TECHNOLOGIES A stakeholder approach for HTA development



Documents

-  [SwissHTA Consensus-Project: Guiding Principles \(627,5 kB\)](#)
-  [SwissHTA Consensus-Project: Cornerstones for the Future Development of HTA in Switzerland \(1,1 MB\)](#)
-  [Slideset SwissHTA \(258,9 kB\)](#)

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Conclusion

- We are at the crossroads: Aging societies, struggling economies – yet unprecedented scientific advance
- Need to take a more holistic approach: too much focus on cost, too little on dynamic efficiency
- New innovative therapies can offer solutions (healthy productive aging, driver of growth and competitiveness)
- Industry needs to live up to societal expectations:
 - innovation
 - value for money
 - corporate social responsibility

„Achieving high value for patients must become the overarching goal of health care delivery, with value defined as the health outcomes achieved per dollar spent.“

Source: Porter ME, Teisberg EO. Redefining health care: creating value-based competition on results. Boston: Harvard Business School Press, 2006.