Why is Health Technology Assessment Important?

Joint BBS and EFSPI HTA Seminar

Allschwil, June 4, 2013

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Acknowledgements

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In Conclusion…
(from BBS Seminar on the convergence of BRA & CER, November 2012)

- Foster a strong collaboration between Clinical R&D, Drug Safety, Health Economics and Marketing with strong biostatistics (quantitative) support in all areas
- Define clear roles and responsibilities to make the most effective use of expertise, skills and resources
- Contribute more case studies on how methodologies are best applied and influence decision making
- Enable effective communication of value evidence generation activities across the whole product life-cycle
- Provide for early engagement and cross-functional alignment on regulatory and market access hurdles
- Be flexible and adaptable to meet a complex and evolving global market environment and still meet needs of patients with best available cost-effective care

Preferred Definitions Differentiate Among EBM, CER, and HTA

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EVIDENCE-BASED MEDICINE (EBM)

- EBM is an evidence synthesis and decision process used to assist patients' and/or physicians' decisions.
- It considers evidence regarding the effectiveness of interventions and patients' values and is mainly concerned with individual patients' decisions, but is also useful for developing clinical guidelines as they pertain to individual patients.

COMPARATIVE EFFECTIVENESS RESEARCH (CER)

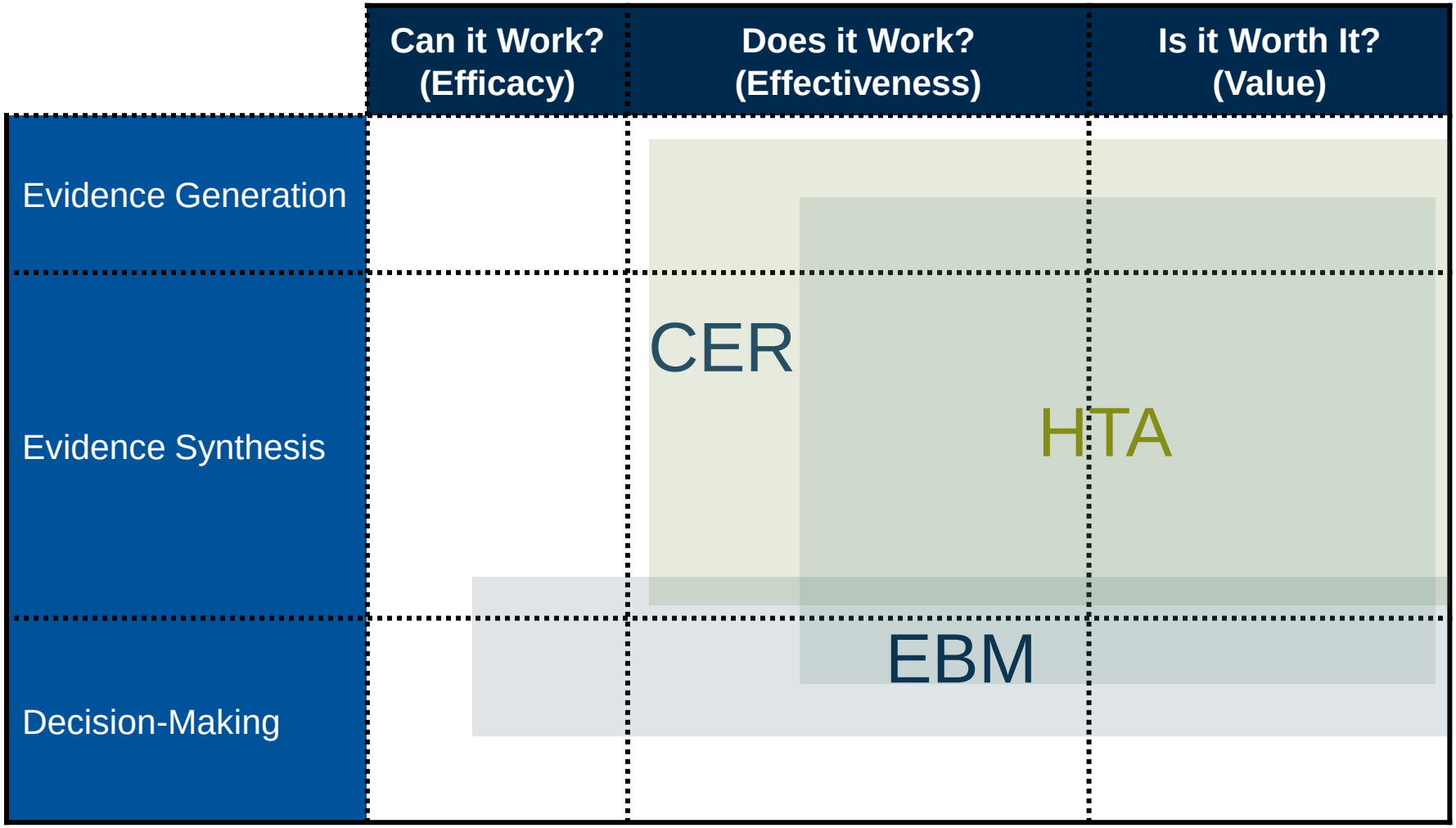
- CER includes both evidence generation and evidence synthesis.
- It is concerned with the comparative assessment of interventions in routine practice settings.
- The outputs of CER activities are useful for clinical guideline development, evidence-based medicine, and the broader social and economic assessment of health technologies (i.e., HTA).

HEALTH TECHNOLOGY ASSESSMENT (HTA)

- HTA is method of evidence synthesis that considers evidence regarding clinical effectiveness, safety, cost-effectiveness, and, when broadly applied, includes social, ethical, and legal aspects of the use of health technologies.
- A major use of HTAs is in informing reimbursement and coverage decisions, in which case HTAs should include benefit-harm assessment and economic evaluation.

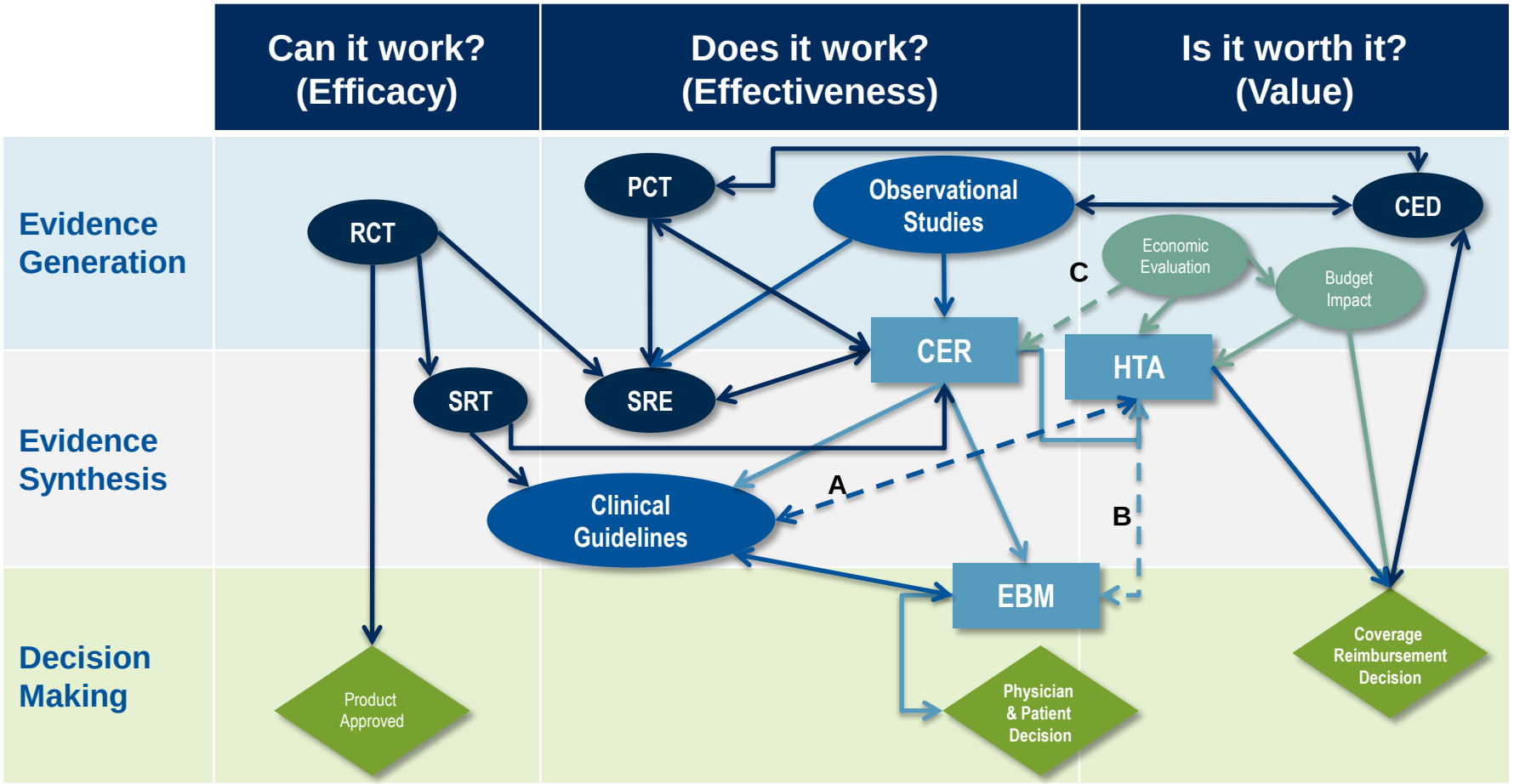
1. Luce BR, Drummond M, Jönsson B, et al. *Milbank Quarterly*. 2010;88(2):256-276

Confusion Exists Concerning Appropriate Definitions of CER, HTA, and EBM



1. Luce BR, Drummond M, Jönsson B, et al. *Milbank Quarterly*. 2010;88(2):256-276.

Redefined Relationships of Evidence Processes



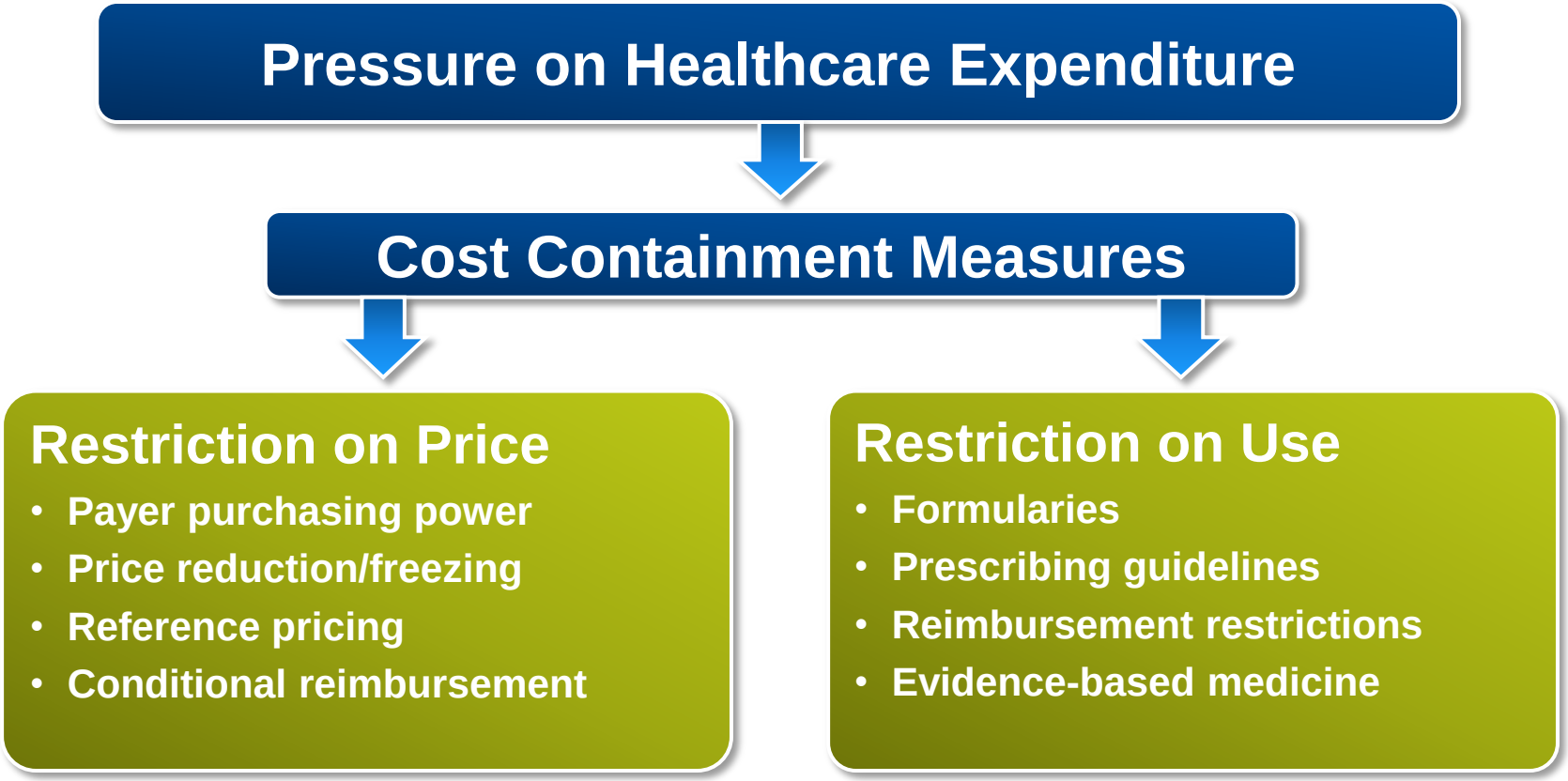
RCT – randomized controlled trial; PCT – pragmatic clinical trial; SRT – systematic review of trials; SRE – systematic review of evidence; CER – comparative effectiveness research; HTA – health technology assessment; EBM – evidence-based medicine; CED – coverage with evidence development.

Solid lines indicate clear relationships, and dotted lines indicated disputed relationships. Diamonds represent decision processes, and circles and ovals represent all other evidence activities, except for the rectangles, which are reserved for EMB, HTA, and CER.

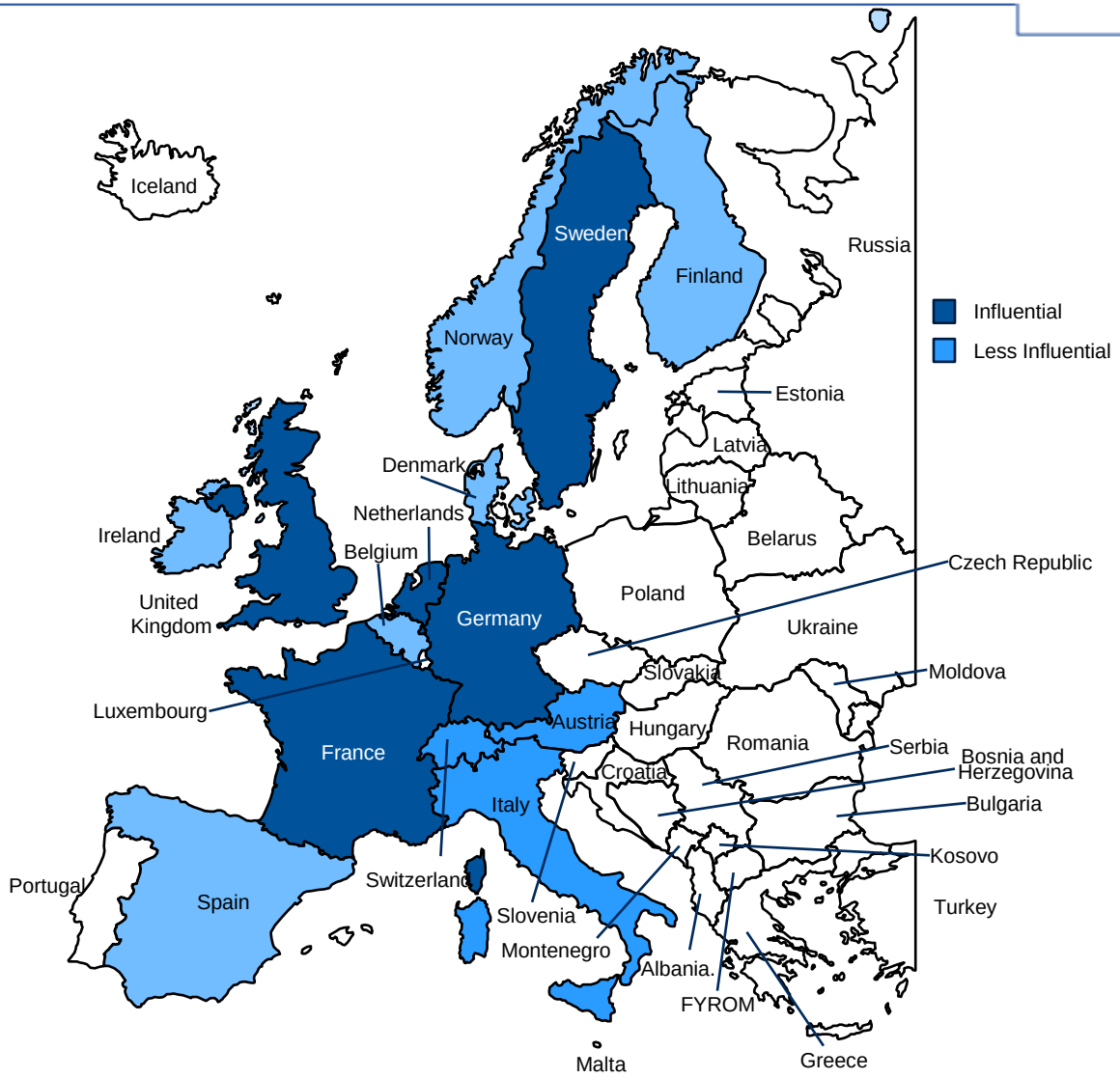
Pricing, Reimbursement, Access

- Pricing is the process of securing a price, usually listed, with a payer
- Reimbursement is securing a payer's funding
- Access is securing product availability in the market with 'use' cost containment measures
- A higher price often implies greater 'use' cost containment measures
- Operationally, reimbursement can refer to specific customer support to secure access for a patient or local institution
  - Training, assistance with submitting paperwork
  - Coding issues
- Pricing, reimbursement, and access depend on evidence of value
  - Evidence of value may be different depending on country, but also at regional or local levels within a specific country

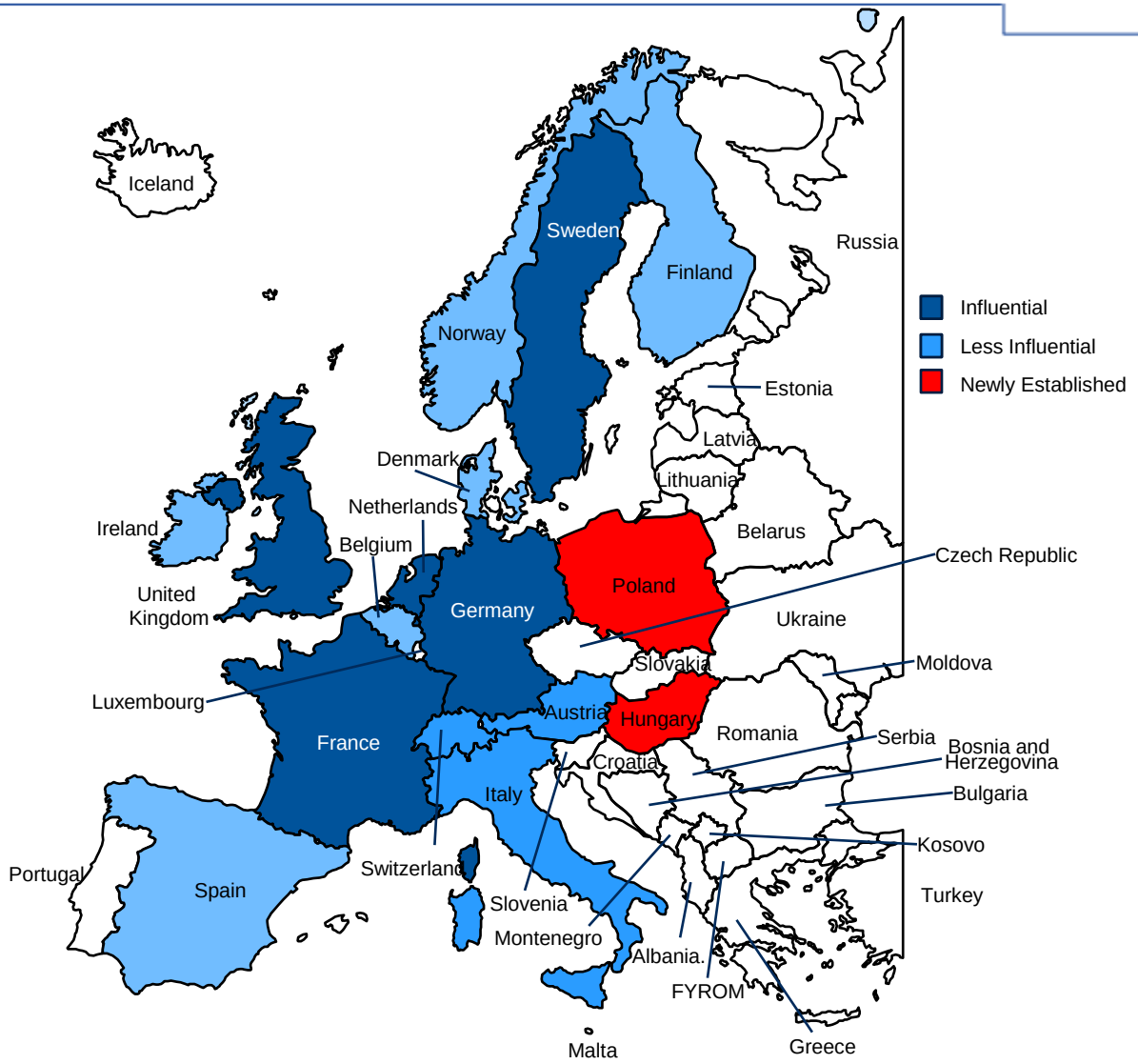
Increasing Costs Are Met With Cost Containment Measures



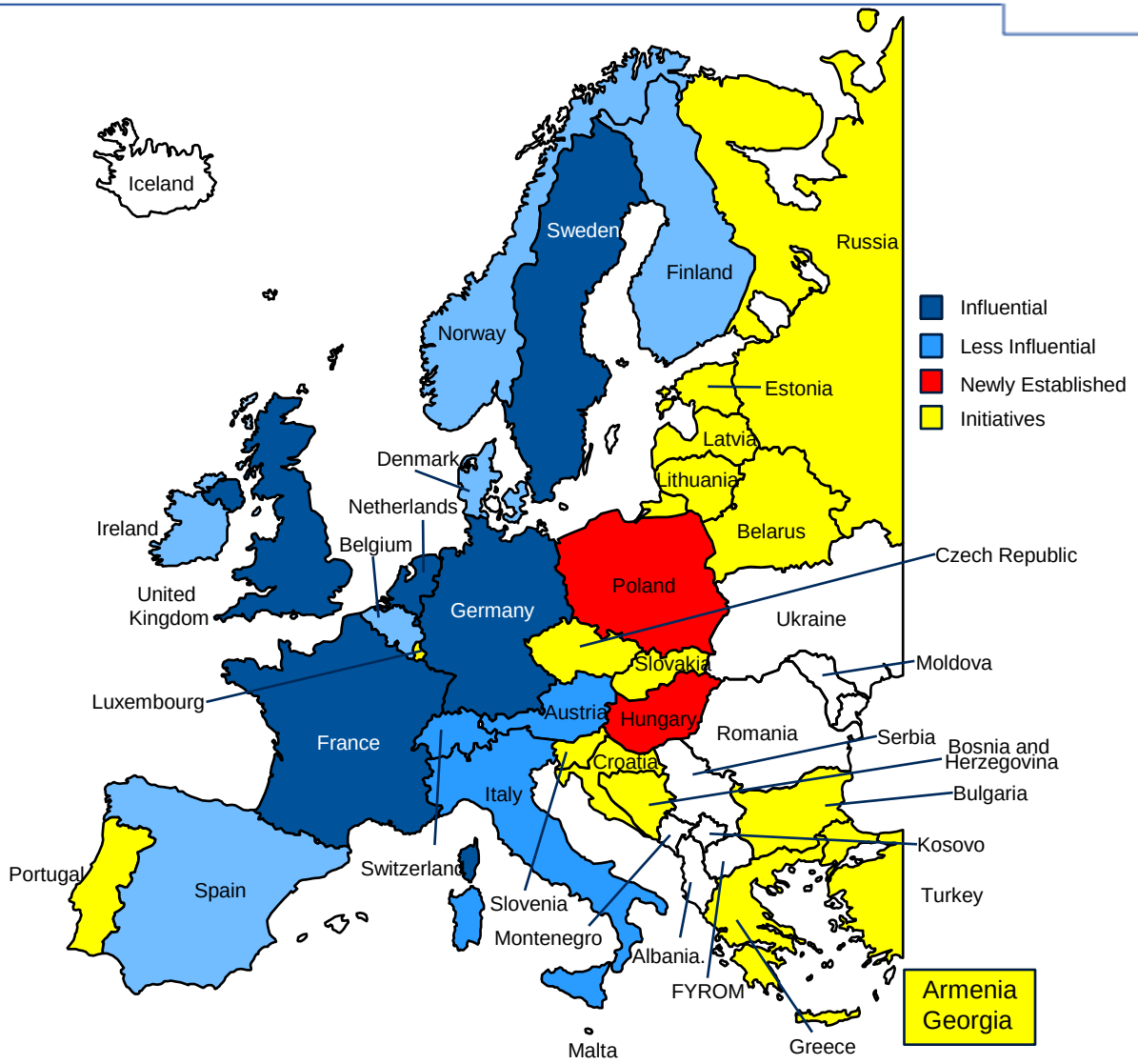
Formal HTA Bodies in Europe



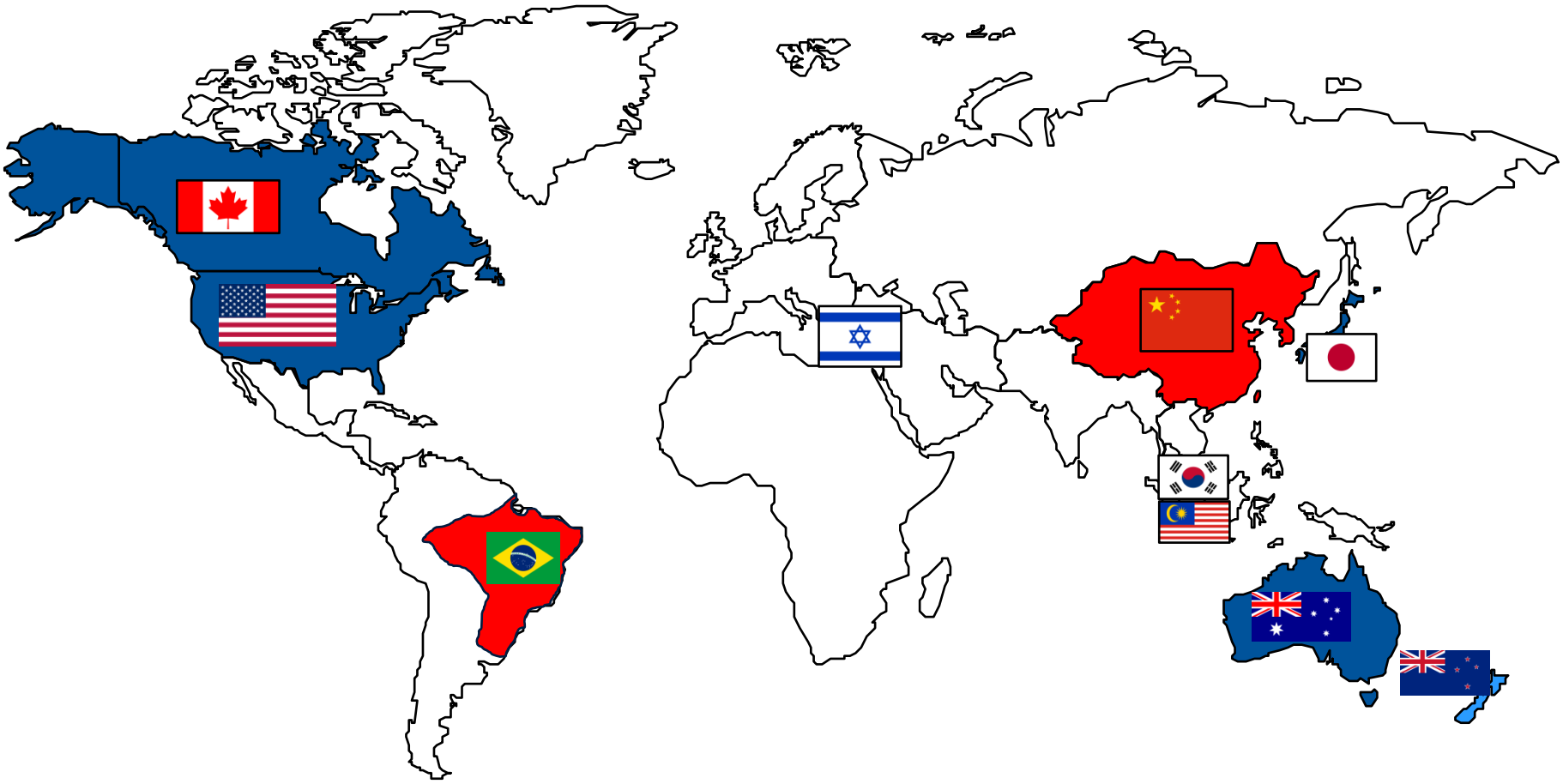
More Recently Established Bodies



Emerging Initiatives



Recent Major Developments

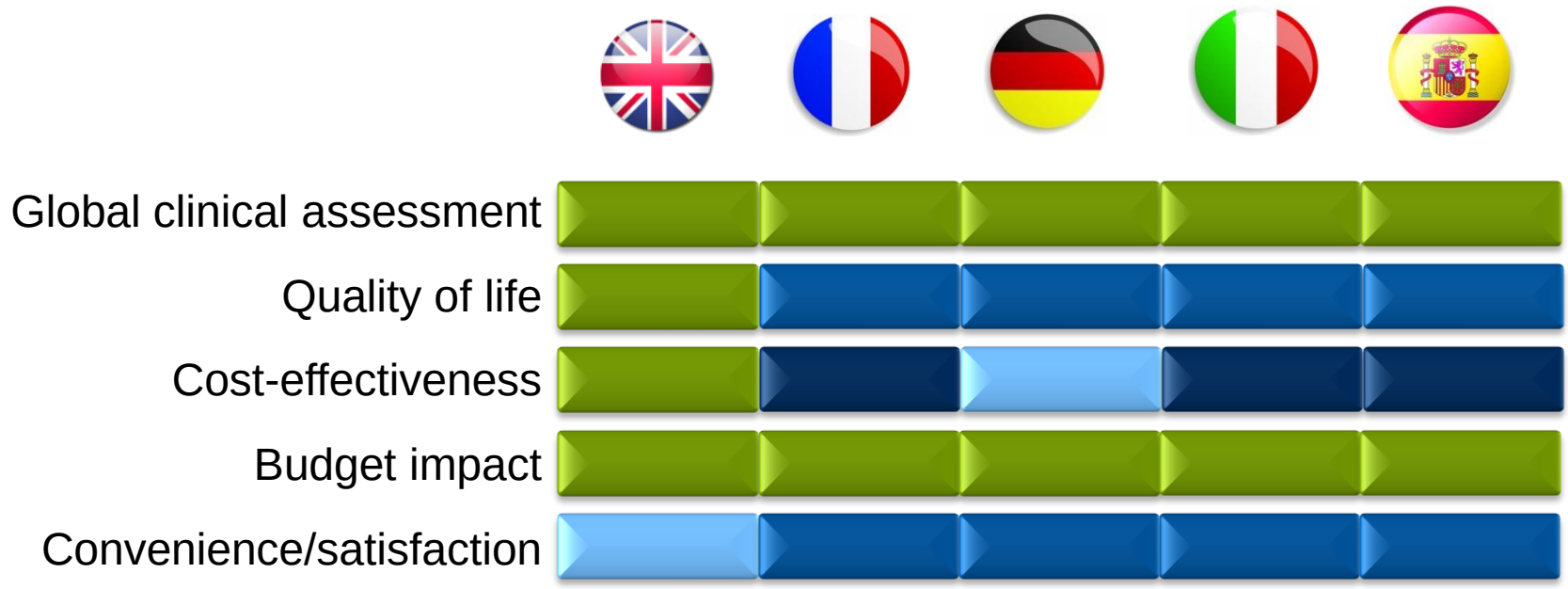


Key Learning

THE HTA WORLD IS CHANGING

- Even though a specific country does not perform formal HTAs today does not mean it will not do so in a few years
- Even though a specific HTA body does not ask for a specific type of evidence today does not mean it will not do so in a few years
- Take into consideration the fact that you will need to prepare for HTA review in an increasing number of geographies
- **REMAIN AWARE OF CHANGES AND PLAN FOR THEM**

HTA Requirements – General Topics



Key Learning

GENERATE THE RIGHT TYPE OF EVIDENCE

- Evidence requirements differ between HTA agencies
- Evidence has to be gathered at all stages of the product development and after launch
- Evidence must be in line with your value message
- **GENERATE THE EVIDENCE THAT WILL ALLOW YOU TO SUBSTANTIATE THE PRODUCT VALUE PROPOSITION**

Reform of the Major HTA Systems

The major European HTA bodies are currently all going through major reforms

NICE

Value-based Pricing vs Free Pricing

- Pricing will be increasingly based on evidence – end of free pricing
- More restrictive application of cost-effectiveness by different thresholds and by indication
- More focus on severity of disease and impact of treatment
- Patient access schemes

IQWIG

Ongoing AMNOG Reform

- Free pricing for 1 year only and negotiations
- Major focus remains on clinical evidence from randomized trials
- Added clinical benefit demonstration will be critical

HAS

Reform of the Appraisal Process

- New appraisal will be a mix between NICE and IQWIG processes
- Focus on added clinical benefit
- Greater importance of economic evidence components

Some general trends:

- Increasing demand for evidence of added value
- More focus toward economic impact
- More pressure on price

Key Learning

MAJOR SYSTEMS ARE CHANGING

- The major HTA systems are going through significant reforms
- The demand for evidence is increasing and evidence generation needs to be carefully planned
- Price pressure is increasing, and obtaining a premium price is strongly linked with premium evidence
- **REMAIN AWARE OF THE CHANGES IN YOUR MAJOR MARKETS AND BE PREPARED TO GENERATE THE APPROPRIATE EVIDENCE TO SATISFY THEM**

Key Learning – Summary

THE HTA WORLD IS CHANGING	• Remain aware of changes happening in the global market and prepare for them
GENERATE THE RIGHT TYPE OF EVIDENCE	• Generate the evidence that will allow you to substantiate the product value proposition
MAJOR SYSTEMS ARE CHANGING	• Remain aware of the changes in your major markets and be prepared to generate the appropriate evidence to satisfy them

Thank You!

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