EC proposal for a regulation on HTA

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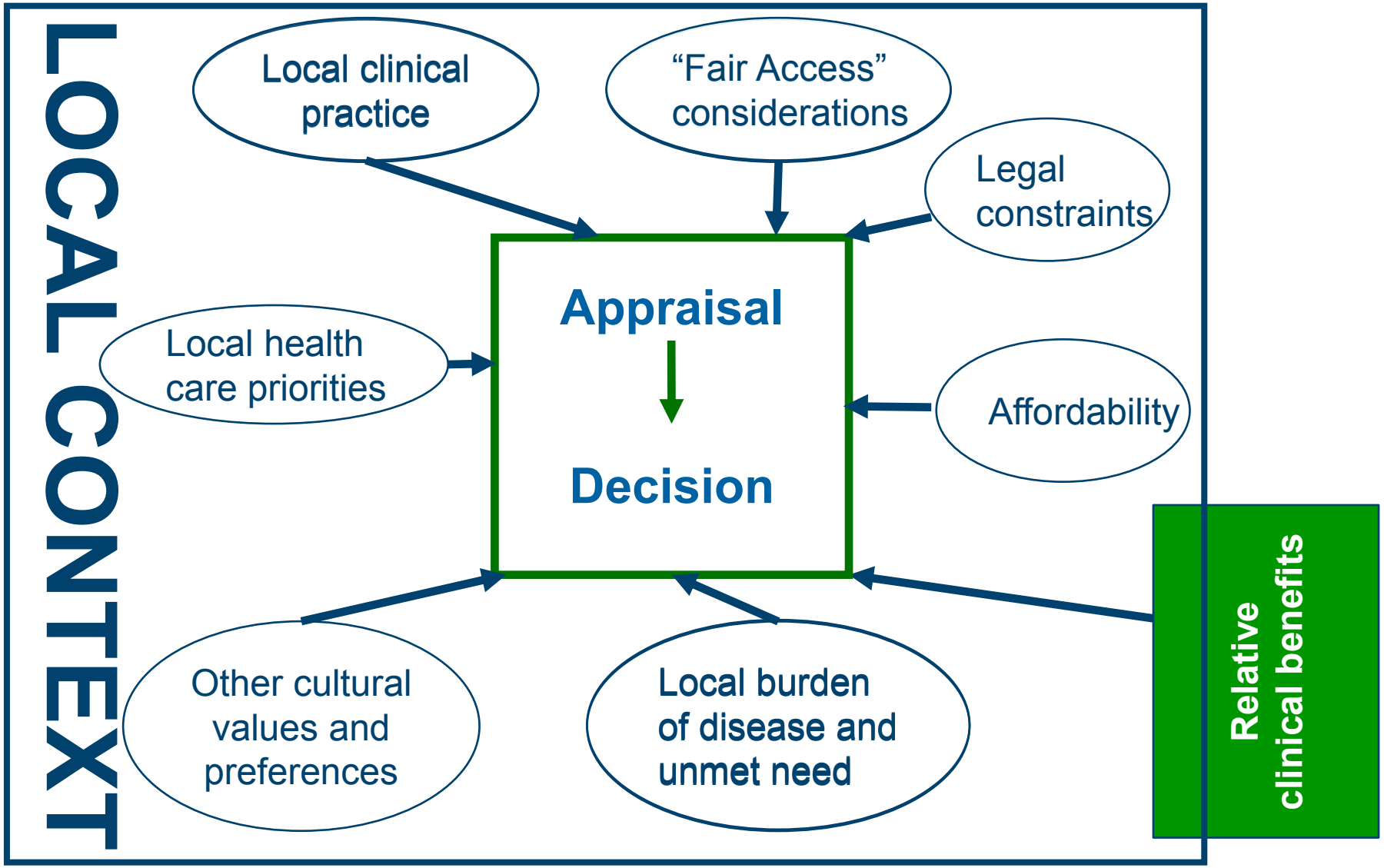
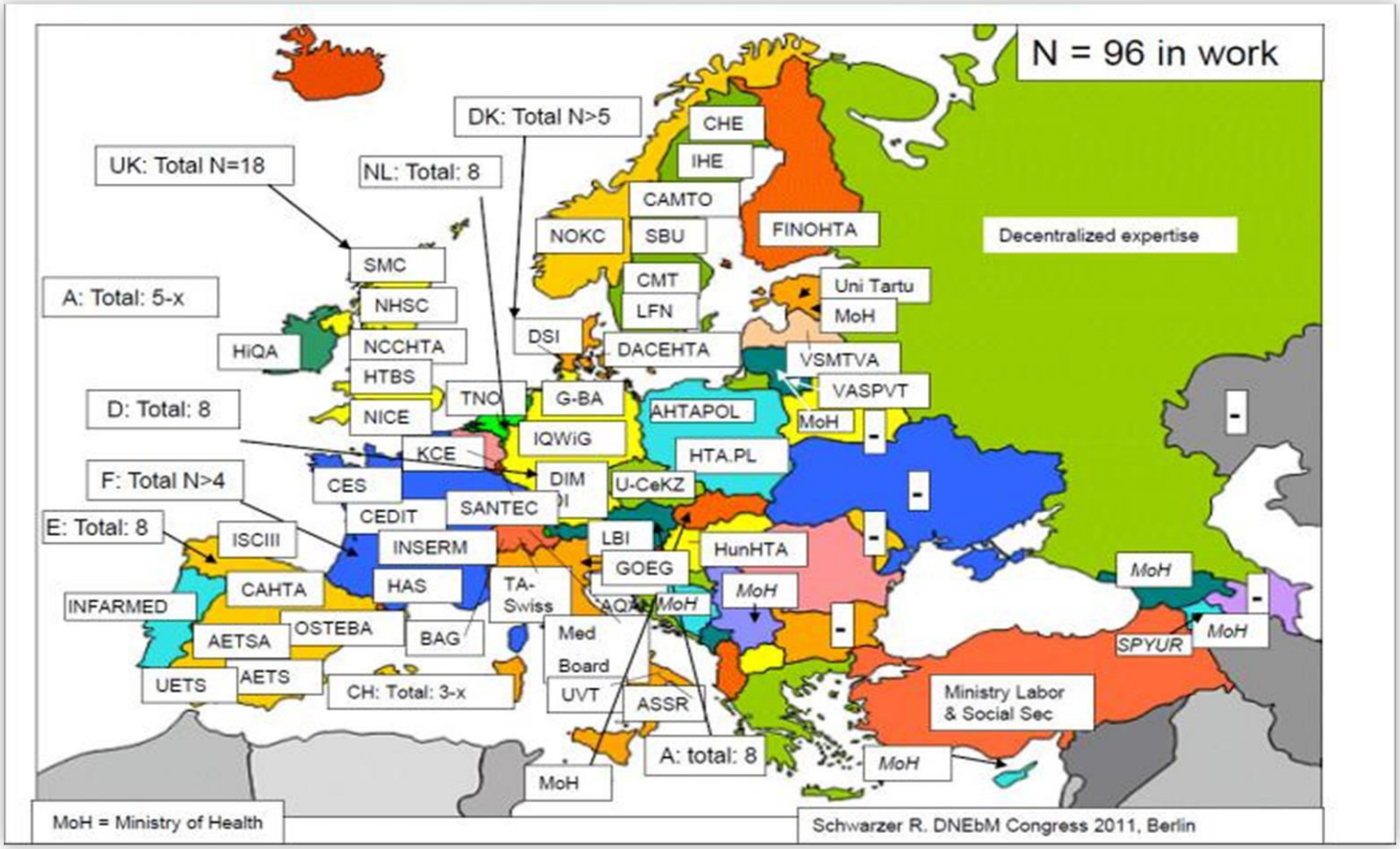
What are we talking about?

Clinical-scientific assessments at the time of launch



HTA keeps us busy

But does this mean that patients and providers have to experience different clinical-scientific assessment standards depending on where they live?



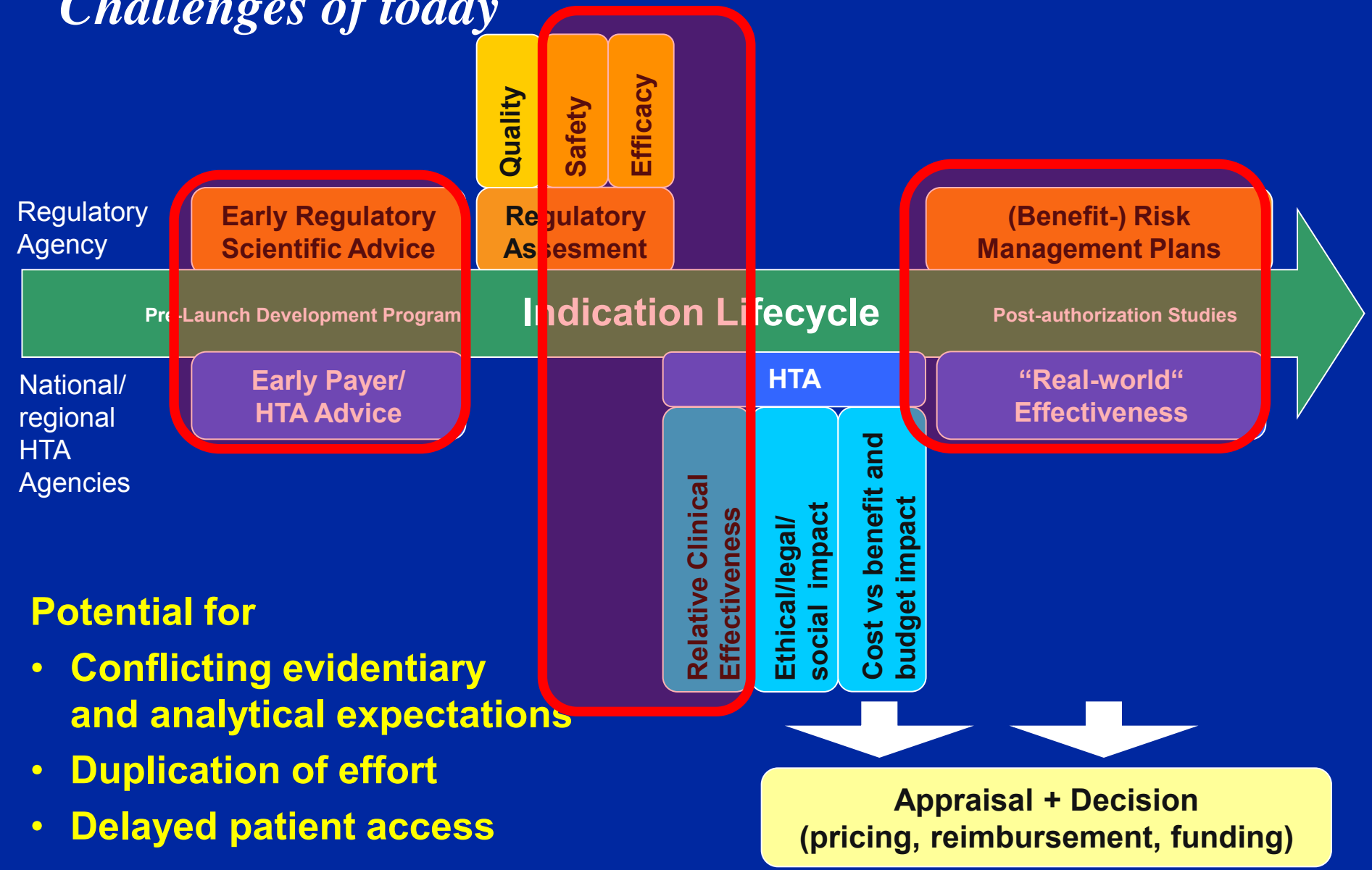
The changing face of biomedical innovation

A different approach to HTA is needed

- Increasing number of medicines with genomic mechanisms and/or genomic biomarkers («co-dependent technologies»)
- Smaller, focused RCTs, adaptive trial designs, expanded use of single-arm trials, surrogate- and intermediate endpoints
- Rare disease innovation with more limited information at the time of (initial) marketing authorization
- Lifecycle approach to medicine development, substantially increased development activity after initial launch
- Faster evolution of clinical «standards of care»
- Innovation to support personalised prescribing of medicines

Regulatory-HTA interface along the lifecycle

Challenges of today



Potential for

- **Conflicting evidentiary and analytical expectations**
- **Duplication of effort**
- **Delayed patient access**

Intensified EU-level collaboration on clinical-scientific benefit assessments

Key advantages from an industry perspective

- Consistency of clinical evidence requirements
- Opportunity to establish an effective interface between regulatory agency and clinical-scientific benefit assessments of HTA agencies
- Predictability of evidence synthesis, timelines and interpretation
- Quality of governance and processes to improve quality of assessments across countries by sharing capacity and capability
- Speed of decision making at national process

More than 20 years of EU HTA collaboration:

Many EU collaborative research initiatives, EUnetHTA, HTA Network, SEED et al.

What has been achieved?	What is still missing?
We know a lot about HTA, different roles in different countries	Sustainable funding and resourcing of EU-level HTA collaboration
Solid understanding of what can be «assessed» at EU-level and what is best left to HTA in Member States	Effective and predictable use of EU-level HTA products in Member States (incentives/disincentives)
Processes for joint EU-level collaboration have evolved over time based on experience gathered in many pilots	Effective involvement of patients and clinical experts in the joint production process
EUnetHTA methodological guidelines	
An emerging interface between EMA and EUnetHTA with focus on early dialogue	
A deep understanding why there is no willingness to act e.g. to change national or regional assessment pathways	
Basic levels of trust established between HTA stakeholders	

EC proposal

Selective topline assessment

What is in it? (selection)	What is missing? (selection)
Focus on clinical-scientific benefit assessments (ie the least context specific HTA domain of all)	a better understanding of what this proposal is about and what not
Recognition of subsidiarity principle: health care system responsibility of Member States (context-specific HTA domains, appraisal, pricing & reimbursement activity)	Strict focus of all available resources on clinical-scientific benefit assessments
Plenty of time (too much?) for stakeholders to adapt (after already >10 years of EUnetHTA)	a clear idea of how not to loose what has been learnt in EUnetHTA so far and how to optimally use JA3 going forward
Framework for joint/parallel scientific consultations (involving EMA)	Sufficient resources to avoid the need for gate keeping «pre-mature» technology appraisals ie discriminating between medicines/technologies that can get such advice
Strict avoidance of duplicative HTA activity in Member States	Clarification of key aspects of joint clinical assessments: scoping process, review/appeal process, timelines, guiding principles re methods
Basic recognition of the need for different HTA framework for different technologies (medicines vs medtech)	Clarification of key aspects of early scientific consultations

Doing now what patients need next