HTA

Creating a system “fit for purpose”

Adrian Griffin | October, 2013

Disclaimer

- Employed by Johnson & Johnson
- Member of NICE Technology Appraisal Committee
- Board of Directors of ISPOR
- Views / observations expressed here are my own

Considerations in developing HTA

- What decision are you seeking to influence?
  - Pricing, reimbursement, coverage, budget
- What resources are available
  - From all stakeholders
- A system needs to be tailored to fit local requirements

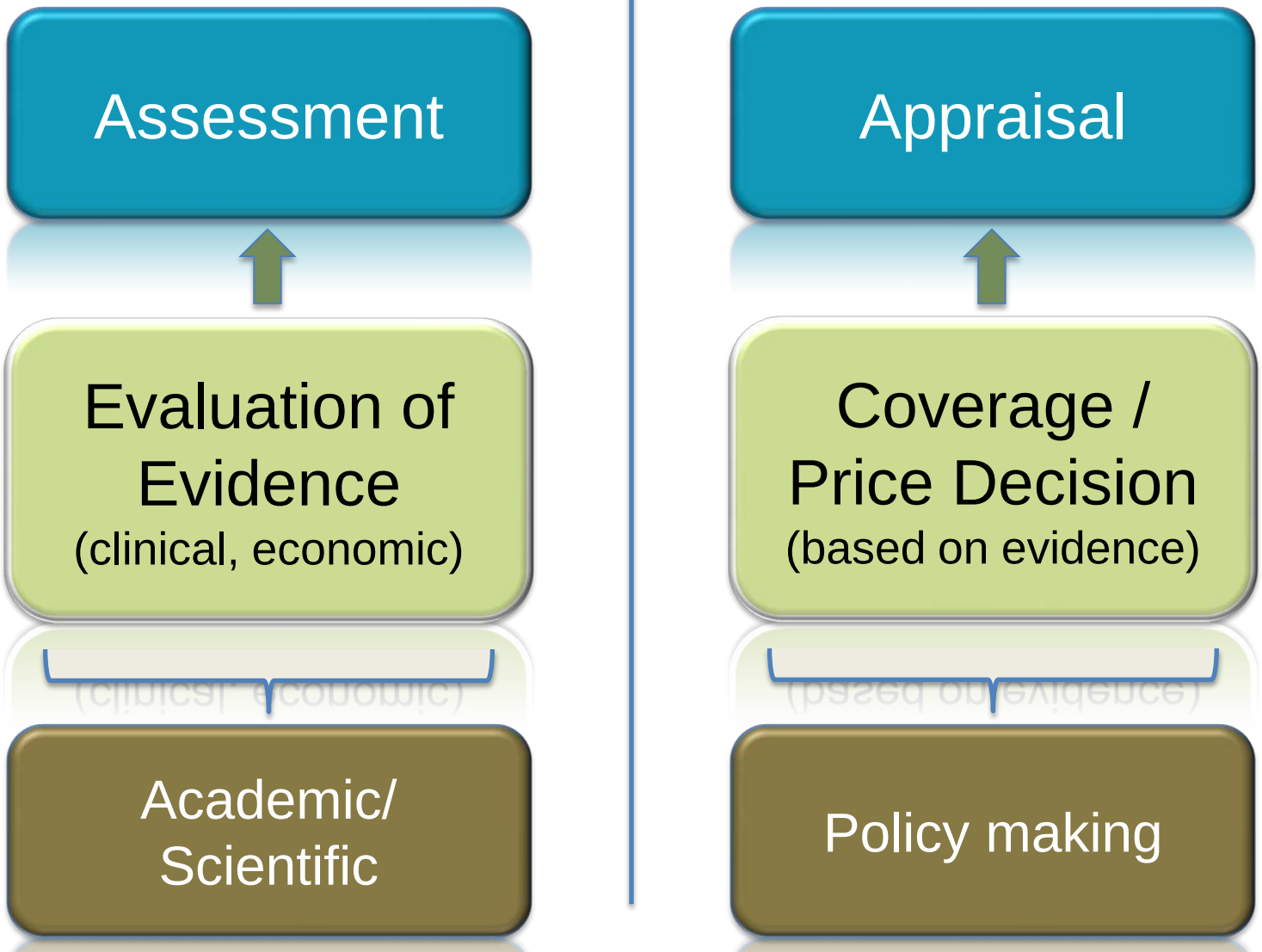
Agenda

- HTA Models and use in Decision-Making
  - Examples from established systems
  - QALYs & Clinical Effectiveness
- Best practice in effective HTA systems
  - International example of good practice
  - Considerations for medical devices
- European collaboration
  - EUnetHTA

Examples of HTA in Action

- There is no single, ‘right’ answer, or model
- There are variations in approach to ‘evaluation’
  - the ‘*assessment’* phase - *the science*
- There are variations in approach to ‘decision making’
  - the ‘*appraisal*’ phase – *the policy making*
- The key is it must be “fit for purpose”, locally
  - Including; clarity of purpose, resourced, tailored to local needs

Use of HTA in decision making



HTA in Reimbursement Decisions

- Two main approaches to assessing value
  - Clinical added value compared with best existing treatment (Ger, Fr)
    - a two step process; clinical, then price

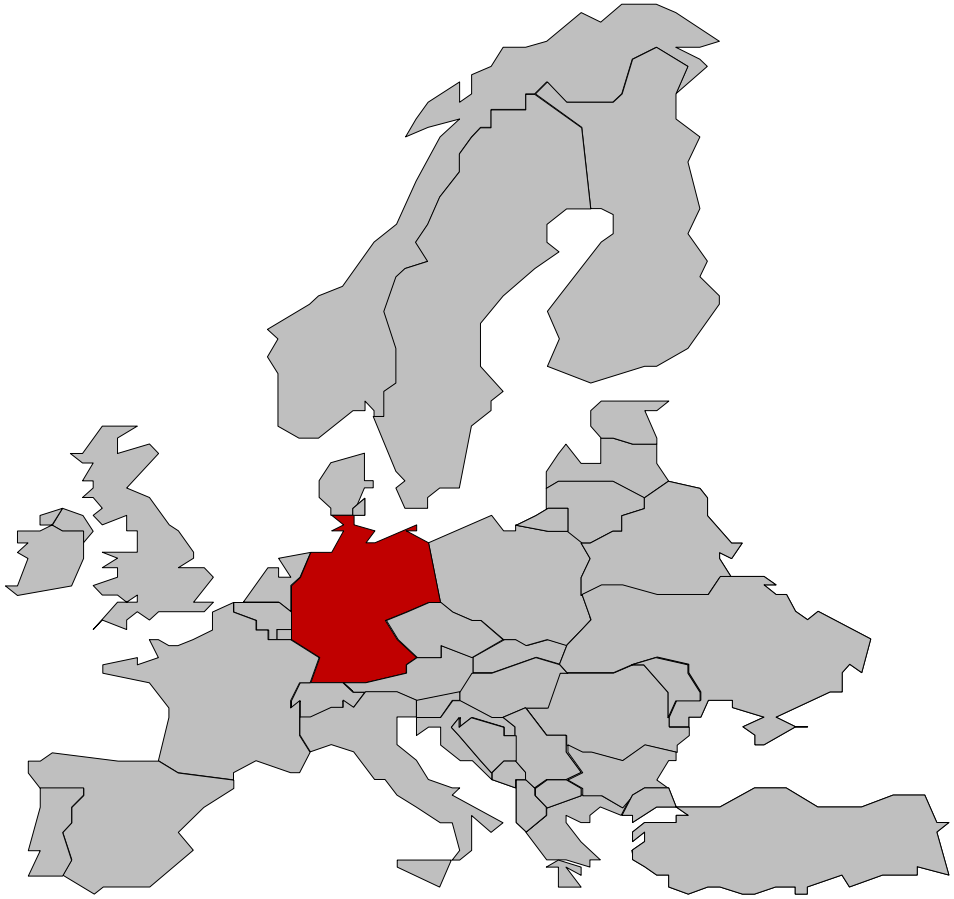
    or
  - Incremental cost utility (£/QALYs) (UK, Aus)
    - a one step process; clinical and economics together

- Two main approaches to coverage decision
  - Manufacturer sets price and HTA is used to assess value and hence coverage/reimbursement in relation to that price *(Y or N)* (Ger, UK)

    or
  - HTA is used to determine value and hence price at which system will cover/reimburse *(Y at $x)* (Fr, Aus)

Examples of HTA in Action

Germany



AMNOG = Arzneimittelmarktneuordnungsgesetz

- “Act for the Restructuring of the Pharmaceutical Market in Statutory Health Insurance ”
- Effective since January 1st 2011

AMNOG: Key Players

Institute for Quality and Efficiency in health care: scientific institute, supports GBA

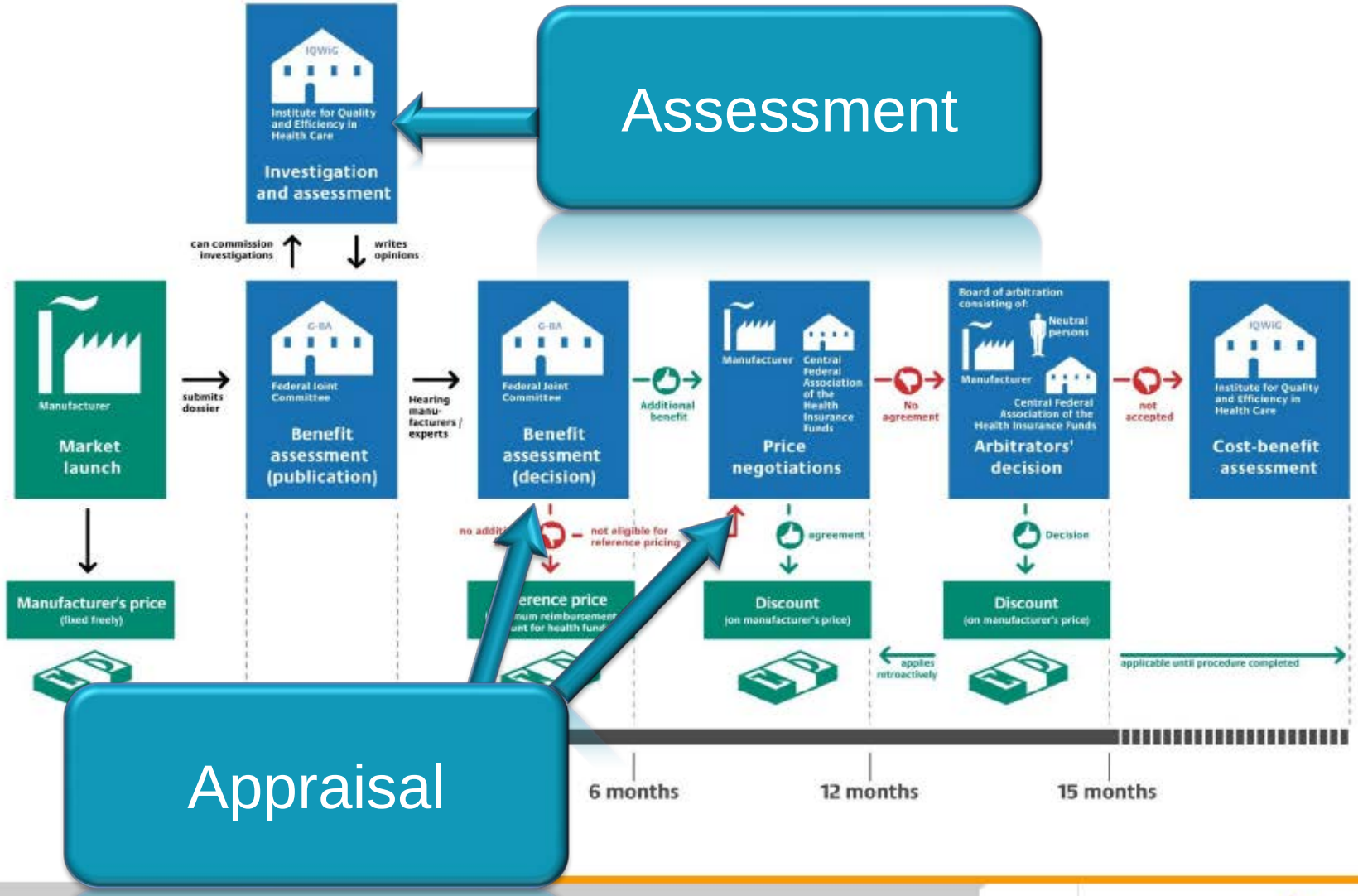
Joint Federal Committee (GBA): Decision body with 13 members (SHI, physicians, hospitals, (patients))

Head association of sickfunds: Negotiation partner for prices

Bundesministerium für Gesundheit

Fair prices for medicinal products

Pricing in the Statutory Health Insurance pursuant to the Act on the Reform of the Market for Medicinal Products (AMNOG)



Gemeinsamer Bundesausschuss

Outcome of benefit evaluation

Determination of the additional benefit (probability)

PROOF	INDICATION	CLUE

Extent of the additional benefit (categorization)

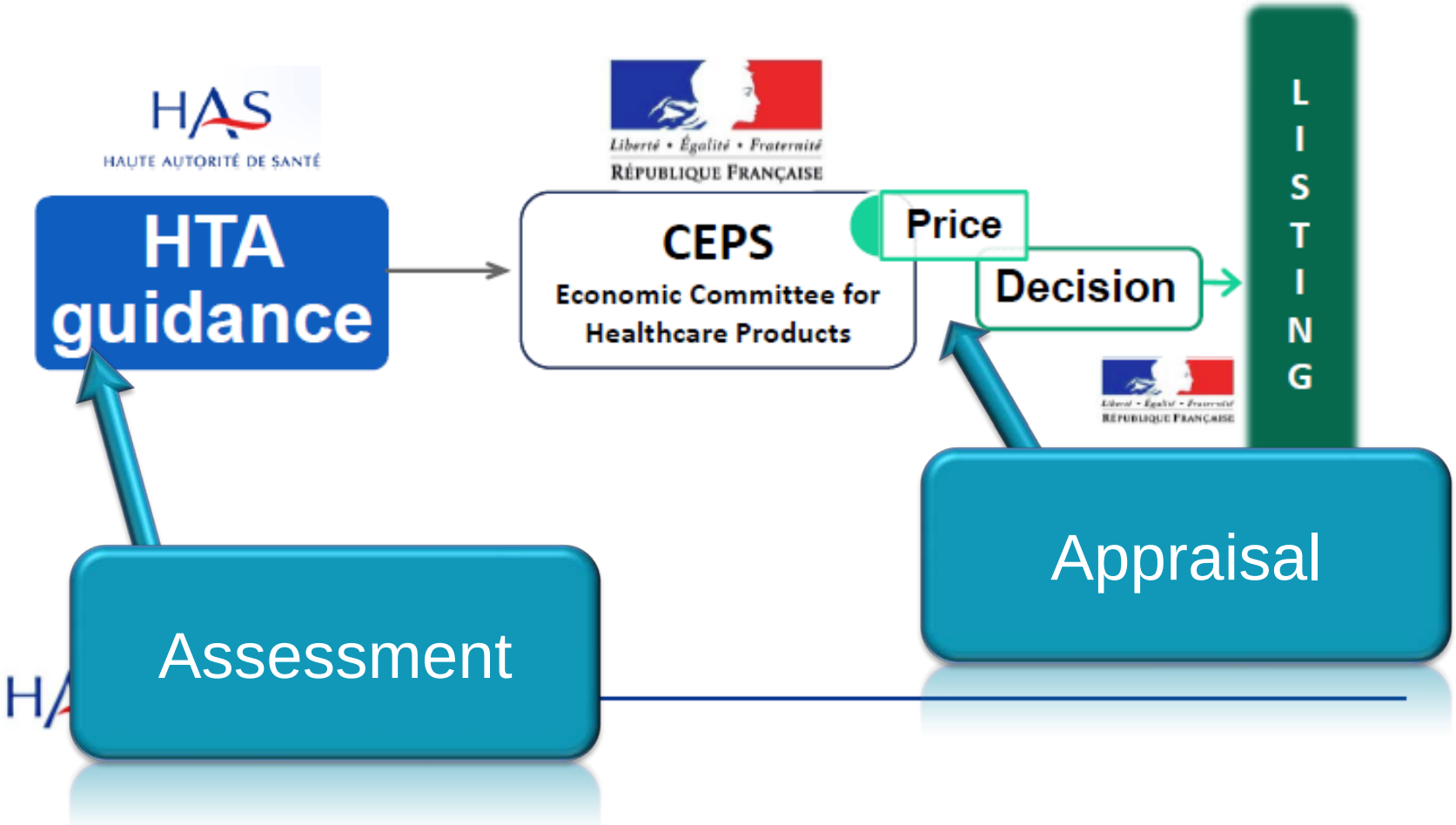
MAJOR	A sustained improvement of the therapy-relevant benefit that was previously unattained compared to the appropriate comparative therapy
IMPORTANT	A significant improvement of the therapy-relevant benefit that was previously unattained compared to the appropriate comparative therapy
SLIGHT	A moderate and not just small improvement of the therapy-relevant benefit that was previously unattained compared to the appropriate comparative therapy
NOT QUANTIFIABLE	Because the scientific data basis does not allow it (non quantifiable can mean anything between slight and major)
NONE	No additional benefit has been demonstrated
SMALLER BENEFIT	The benefit of the medicinal product to be assessed is smaller than the benefit of the appropriate comparative therapy

Source: www.vfa.de

France

HAUTE AUTORITÉ DE SANTÉ

HTA, Reimbursement and Pricing for a new drug: The main actors



Added Clinical benefit (ASMR) and Price

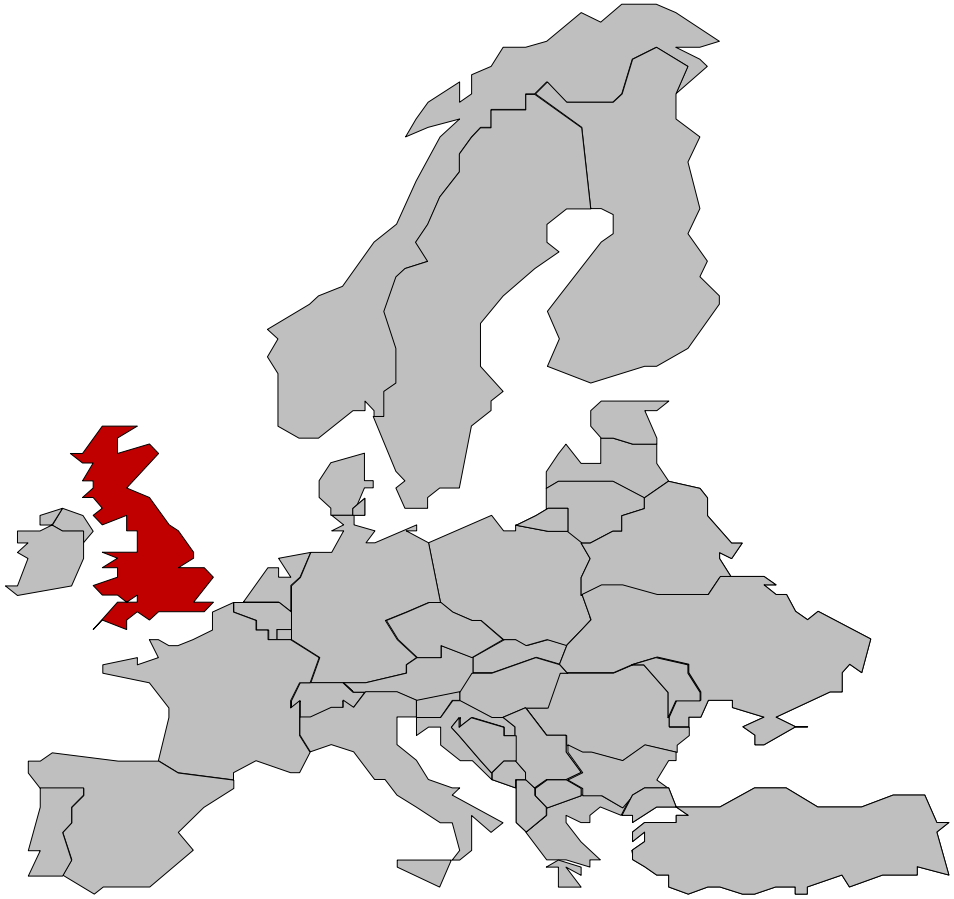
Added clinical benefit	ASMR	Price
Major Important Moderate	I II III	Higher Price than comparators. « European » price accepted.
Minor	IV	No important difference in price / comparator
No Added Clinical benefit	V	Reimbursement ONLY if price inferior to comparators

HAS

Clinical added benefit in France and Germany

France ASMR	Germany Added benefit
Level I : Major ASMR	Major added benefit
Level II: Important ASMR	Considerable added benefit
Level III: Moderate ASMR	Minor added benefit
Level IV : Minor ASMR	Not quantifiable added benefit
Level V : No ASMR	No added benefit
Not eligible to reimbursement	Less benefit

UK

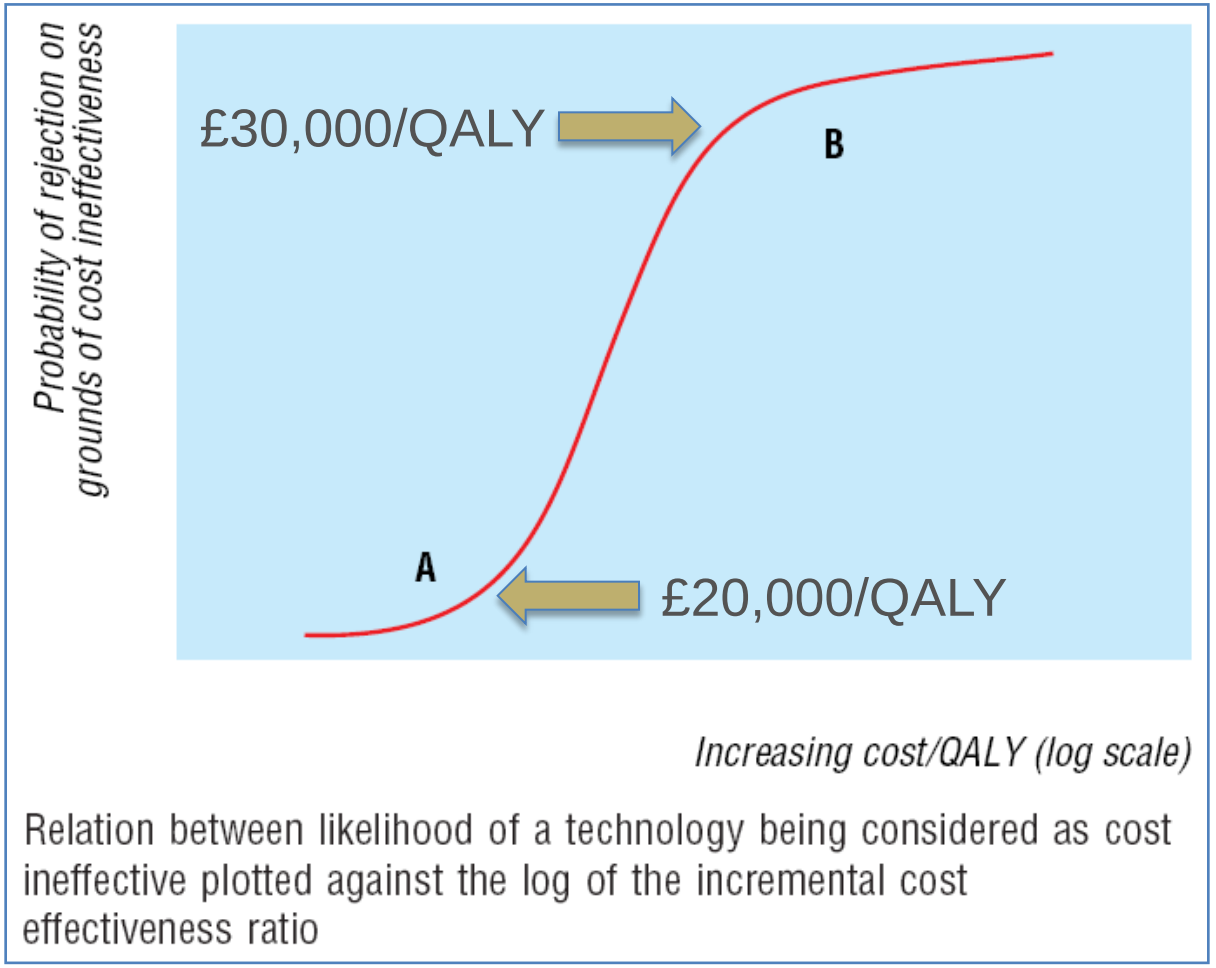


NHS
National Institute for
Health and Clinical Excellence

NICE National Institute for Health and Care Excellence

NICE Decision Making

Cost Effectiveness

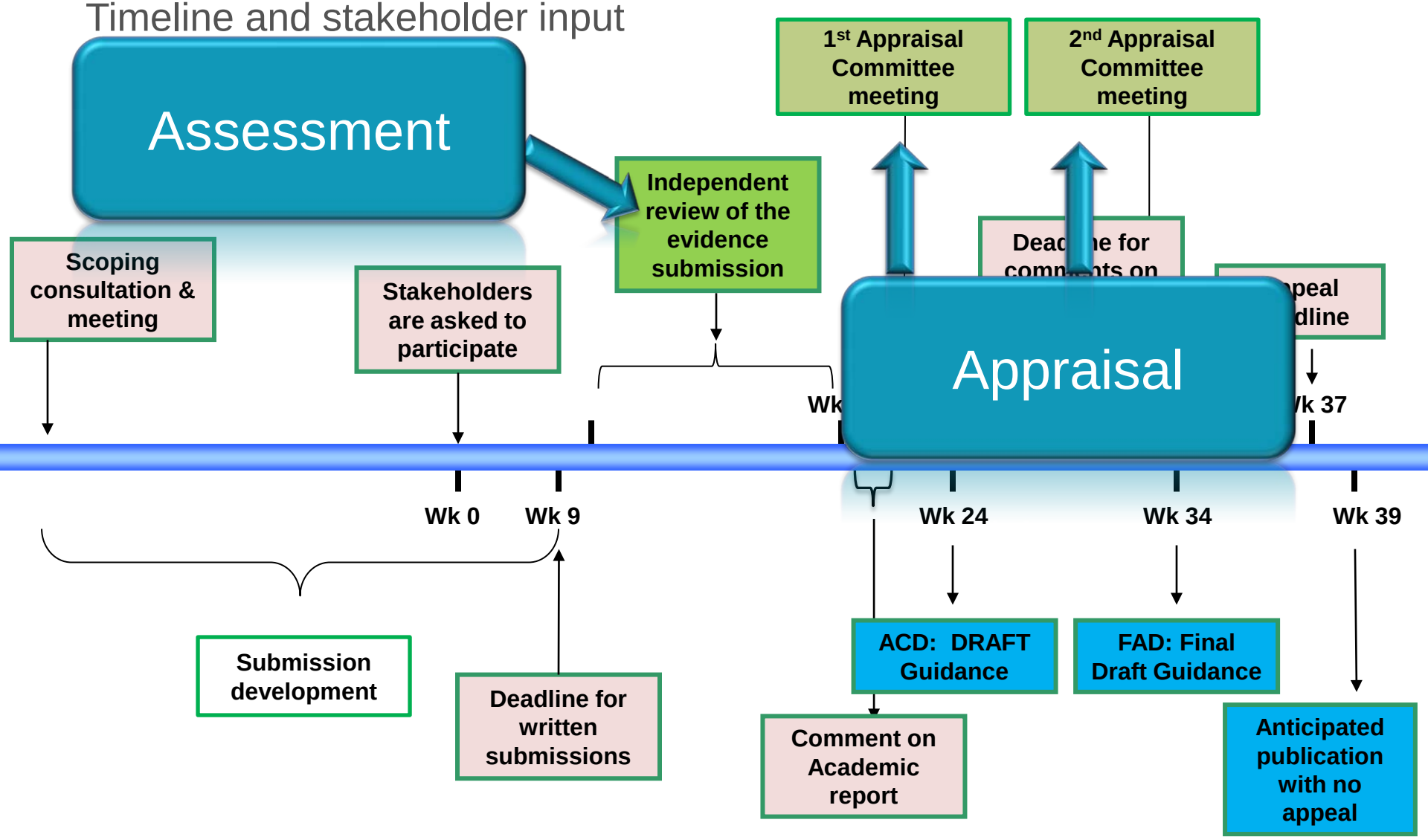


Relation between likelihood of a technology being considered as cost ineffective plotted against the log of the incremental cost effectiveness ratio

Rawlins & Culyer BMJ 2004; 329: 224-227

UK: NICE Technology Appraisal Process (STA)

Timeline and stakeholder input



NICE and Pricing

- Present
  - Manufacturer sets price
    - NICE use £/QALY to assess value and coverage @ that price
      - NB: manufacturer can propose access scheme

Y/N Coverage Decision based on:

Costs (inc FIXED price) / FIXED Benefits = **Y/N Decision based on £/QALY Threshold**

- Future – Value-based pricing
  - HTA used to determine value and hence price at which NICE will cover/reimburse (possible 'modifiers' for burden, unmet need etc)

Price & Coverage Decision based on:

Value (£/QALY Threshold) / FIXED Benefits = **Costs (inc price)..... *Price negotiation***

The Local situation dictates how HTA influences access – even within the same 'model'

One Drug, Three Countries, Three Decisions

Ref: Using Effectiveness and Cost-effectiveness to Make Drug Coverage Decisions: A Comparison of Britain, Australia, and Canada. Clement FM, *et al*., *JAMA.* 2009;302(13):1437-1443.

- Review of Reference:
  - Using Effectiveness and Cost-effectiveness to Make Drug Coverage Decisions: A Comparison of Britain, Australia, and Canada. Clement FM, *et al*., *JAMA.* 2009;302(13):1437-1443.

All Combinations of Models Used

Determined by local priorities, values, and legislation

Assessment model / Decision approach	Clinical added value (*2 step*)	QALY (*1 step*)
Manufacturer 'free' pricing	Germany	UK
Negotiated pricing	France	Australia

Pros and Cons of the Two Main HTA Models

	QALY	Relative Effectiveness
Country	**Australia, Canada, UK**	**France, Germany, Japan**
Concept	**Cost/QALY Vs ICER Threshold**	**2 steps: 1) Clinical benefit 2) Price negotiation on "added value" and Budget Impact**
Applicability & Learnings	*Difficult for non-health economists to understand?* *Technical limitations; eg- end of life or discounting data availability* *What is the right threshold?*	*Clinical benefit focus more understandable for patients and public?* *What is the right local comparator?* *Less resource intensive?*

The value (and limitations) of HTA

A tool for value – not affordability

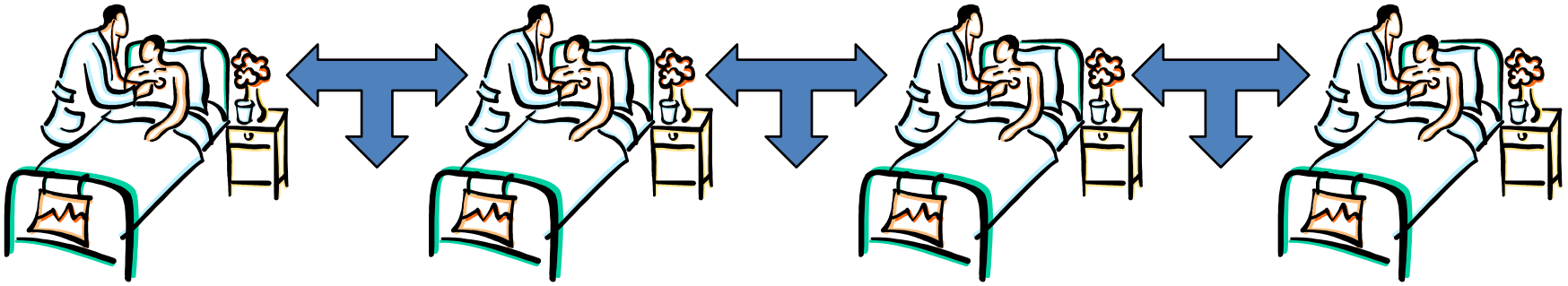
Why we may not see cost savings from medical advancements

One hospital bed
Many willing patients!

Bed re-filled

Bed re-filled

Bed re-filled



Drug Therapy Moves patient from hospital to home

LOS reduced by use of Laparoscopic Surgery rather than open

Minimally invasive techniques move treatment to out-patient setting

Best Practice in Effective HTA Systems

What makes an efficient & effective HTA?

International example of good practice

The HTA & decision making processes should be **transparent,** and respect commercial data confidentiality

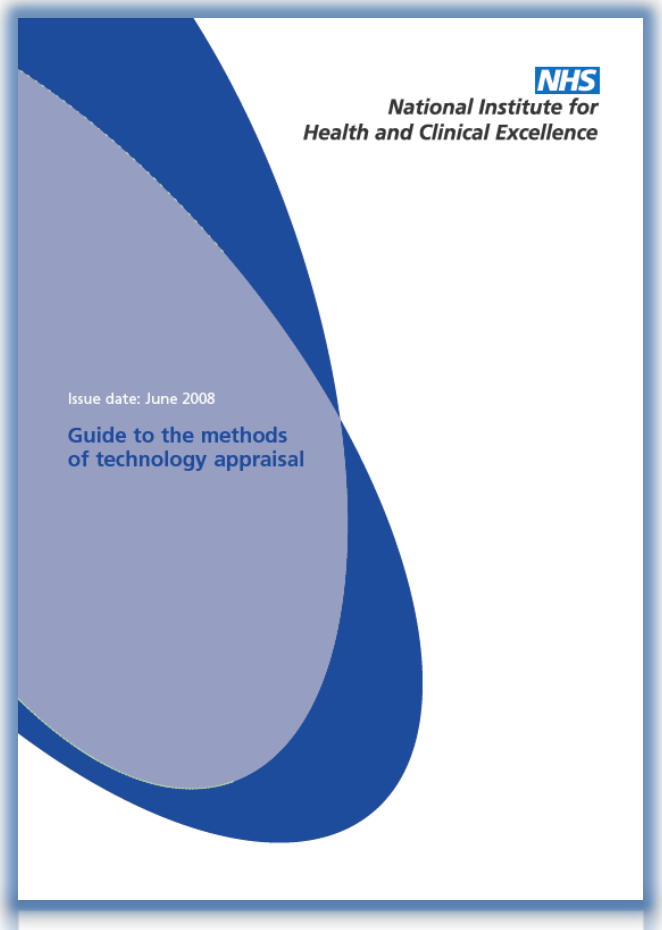
Transparency in process and methods

The

- ‘What’ &
- ‘When’

The

- ‘How’



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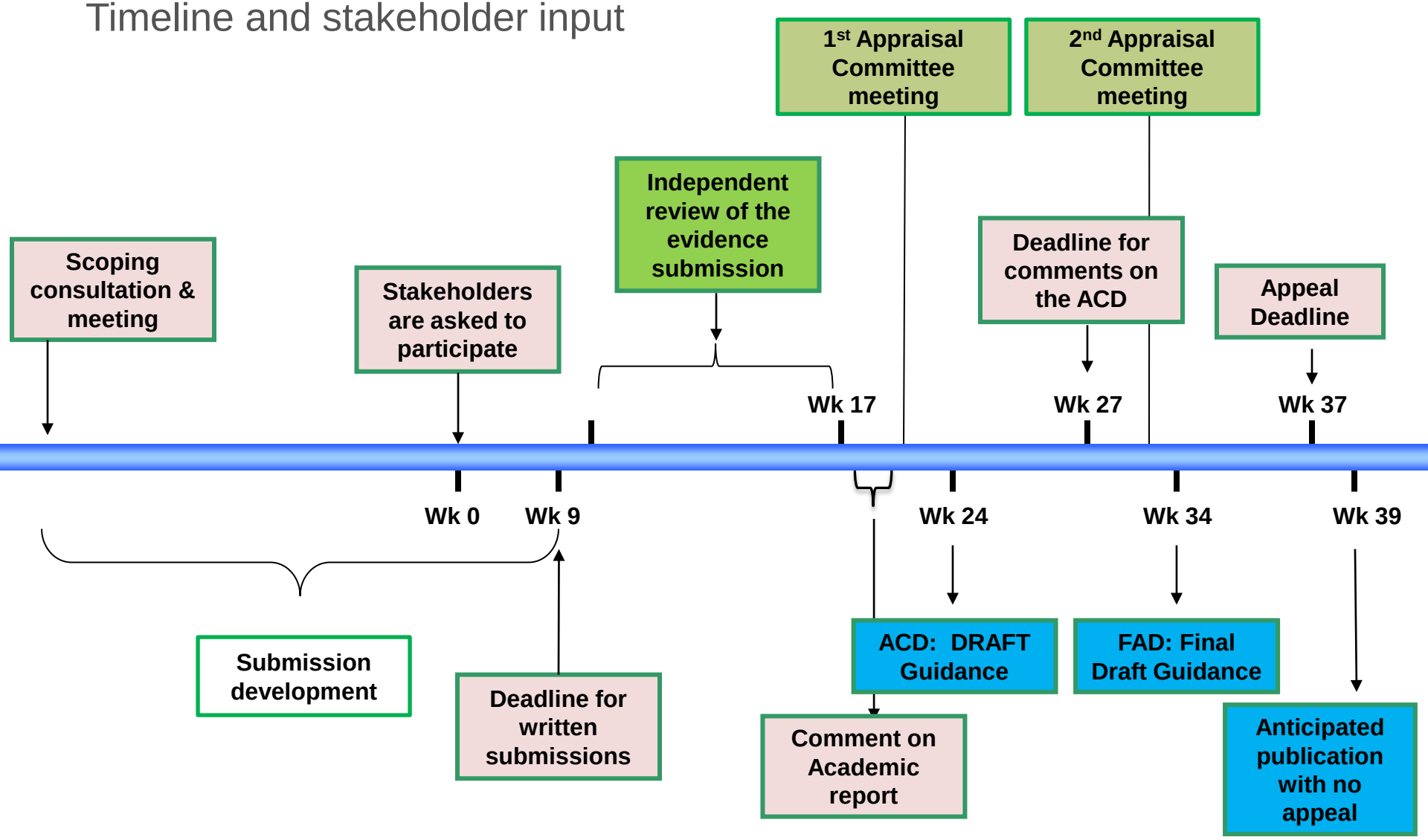
Timeline and stakeholder input



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Independence between evaluators, decision-makers and payers

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HTA process should be **accountable**, with an appeals process

HTA needs to be **applicable locally**, and cannot be translated verbatim across boarders

eunethta

- Extract from EUnetHTA Strategy;
  - In order **to maximise the relevance of HTA** for decision making, it needs to be **undertaken within the policy context of the country** rather than at the European level. Policy context **takes into account national priorities and systems, as well as cultural and social differences.**

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Product **evidence should be respected**, and class effects not extrapolated inappropriately

What makes an efficient & effective HTA?

International example of good practice

- Regulatory and HTA should remain independent
- New evidence should be able to be reviewed through product lifecycle
- Pricing to be left to the developers, according to free market principles
- All appropriate evidence should be considered (not only RCTs)
- HTA should take the societal perspective, and not focus on silos
- HTA should speed access to innovation where C-E demonstrated
- HTA should not be used covertly for cost containment or rationing

Additional considerations for HTA of Devices and Diagnostics

Considerations for HTA of Medical Devices

- Outcomes differences
- Identification differences
- Learning differences
- Organisational differences
- Usability differences
- Price differences

- Diagnostic v therapeutic
- Difficulty of RCTs / Blinding
- Improved outcomes with experience
- Benefit from system redesign – shift in setting
- User preference / ability
- Miss-alignment between HTA and procurement on value

Complexity of Device Pathways in Europe

- Regulatory: Always
- HTA: Sometimes
- Reimbursement: More often by procedure
- Procurement: Local not national

European Collaboration
EUnetHTA

What is it?
Who is involved?
What are they doing?

eunethta

(European network for Health Technology Assessment)

- **Mission**
- To support collaboration between European HTA organisations that brings added value to healthcare systems at the European, national and regional level.

- **EUnetHTA Strategic Objectives**
- Better coordination of HTA activities
- Less duplication

} More effective use of national resources

- Increase HTA output, and input to decision-making in the Member States and EU
- Strengthen the link between HTA and healthcare policy making
- Support countries with limited experience with HTA


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REGIONE DEL VENETO
NHR Evaluation, Trials and Studies Coordinating Centre
NHS
National Institute for Health Research
NICE
National Institute for Health and Care Excellence
RegioneLombardia
jazmp
Javna agencija Republike Slovenije za zdravila in medicinske pripomočke

Road to European Collaboration

DIRECTIVES

DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 March 2011

on the application of patients' rights in cross-border healthcare

Article 15

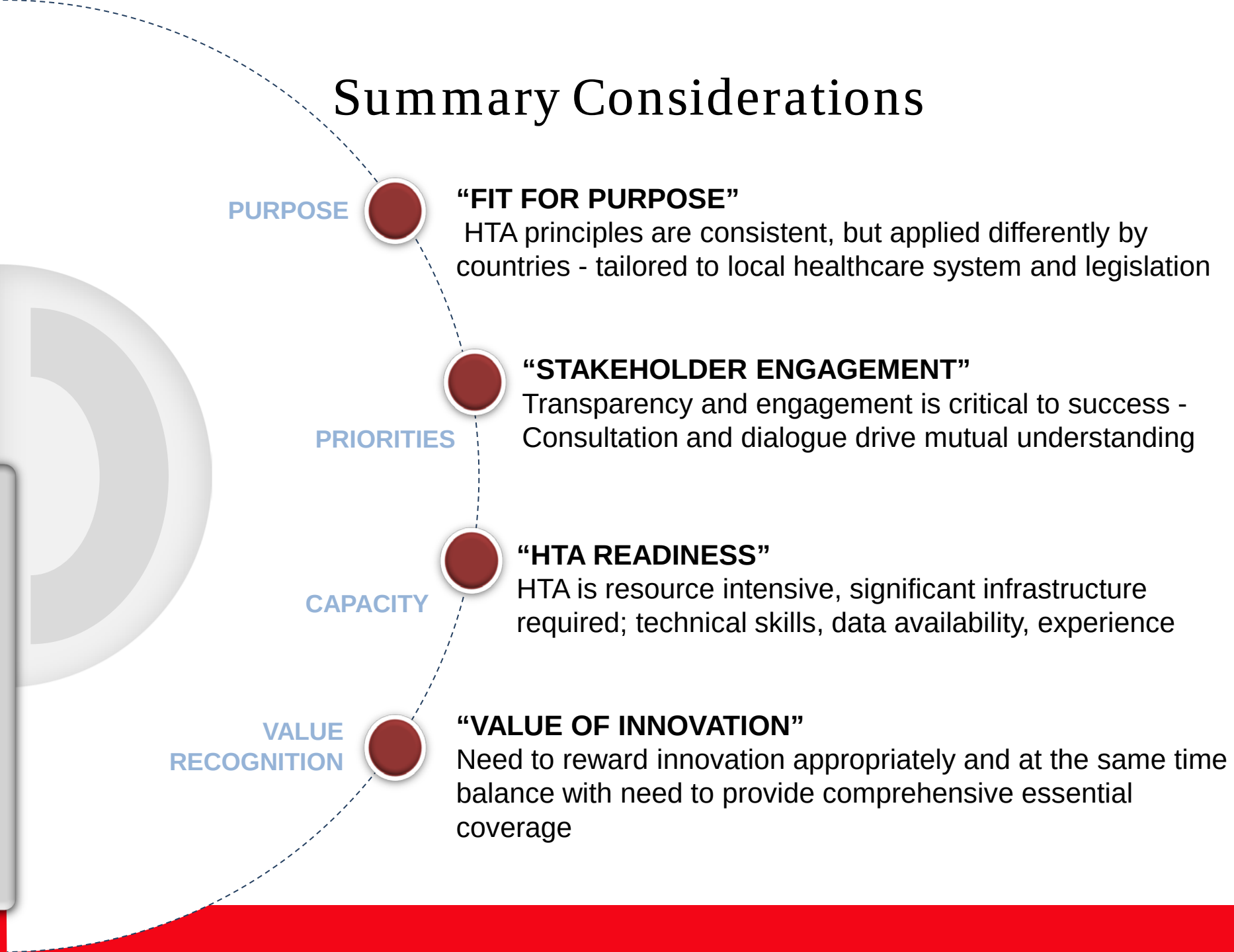
Cooperation on health technology assessment

1. The Union shall support and facilitate cooperation and the **exchange of scientific information** among Member States within a **voluntary network connecting national authorities** or bodies responsible for health technology assessment designated by the Member States.

Potential areas for collaboration

- Collaboration on Relative Effectiveness Assessments
  - Alongside MAA for Pharmaceuticals
- Methodology development and education materials
- Early Scientific Advice (Dialogues) for developers
- Collaboration on evidence gaps/generation

Summary Considerations



“FIT FOR PURPOSE”
HTA principles are consistent, but applied differently by countries - tailored to local healthcare system and legislation

“STAKEHOLDER ENGAGEMENT”
Transparency and engagement is critical to success - Consultation and dialogue drive mutual understanding

“HTA READINESS”
HTA is resource intensive, significant infrastructure required; technical skills, data availability, experience

“VALUE OF INNOVATION”
Need to reward innovation appropriately and at the same time balance with need to provide comprehensive essential coverage

Thank you

Questions?