



HAUTE AUTORITÉ DE SANTÉ

Health Technology Assessment in Europe: Towards harmonisation?

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ESMO September 2012



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The context

Background: Single market , national healthcare systems

- **Europe = single market**
 - Marketing Authorisation: European legislative framework since 1965, European Medicines Agency since 1995
- **Healthcare systems: funded and organised by Member States**
 - Healthcare organisation, decision making criteria and procedures are decided by Member States.
 - This includes Drugs reimbursement, choice of HTA institution(s), criteria...

Pricing and reimbursement

Two-step procedure in most cases

1. Health Technology Assessment:
2. Decision making on reimbursement
± Price

HTA : Definition

- *HTA* is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a **systematic, transparent, unbiased, robust** manner
- Its aim is to **inform** the formulation of safe, effective, **health policies** that are **patient focused** and seek to achieve **best value**
- Despite its policy goals, HTA must always be **firmly rooted in research** and the **scientific method**

Source: EUnetHTA

Drugs reimbursement: the context

- **Reimbursement / Pricing systems for drugs very different accross Europe**
 - Positive list vs Negative list
 - Systematic or selective assessment
 - Price taking countries (cost effectiveness analysis on the basis of the price decided by the company) vs price setting countries (Price negotiating or Price setting committee on the basis of the assessment of the added clinical benefit of the drug)
 - Financing, decision making, drug evaluations made at at national or « regional » level

Common principles and challenges...

- **Common elements for assessment**
 - Clinical benefit to the patient in ‘real-life’ situation
 - Nature and magnitude of the improvement over existing therapies
 - ...
- **Common issues and challenges:**
 - e.g. Innovative technologies:
 - How to reduce uncertainties after product launch
 - ...



02

**What support for
HTA cooperation
in Europe?**

HTA cooperation in Europe:

From 3-year projects to a permanent network

- **3-year projects** have been run at European level, with a support from the European Commission

European Network for Health Technology Assessment EUnetHTA

- First EUnetHTA project 2006-2008
 - EUnetHTA as a Joint Action 2010-2012
 - Future EUnetHTA Joint Action 2 2012-2015
- Set up of a **permanent network**
 - 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

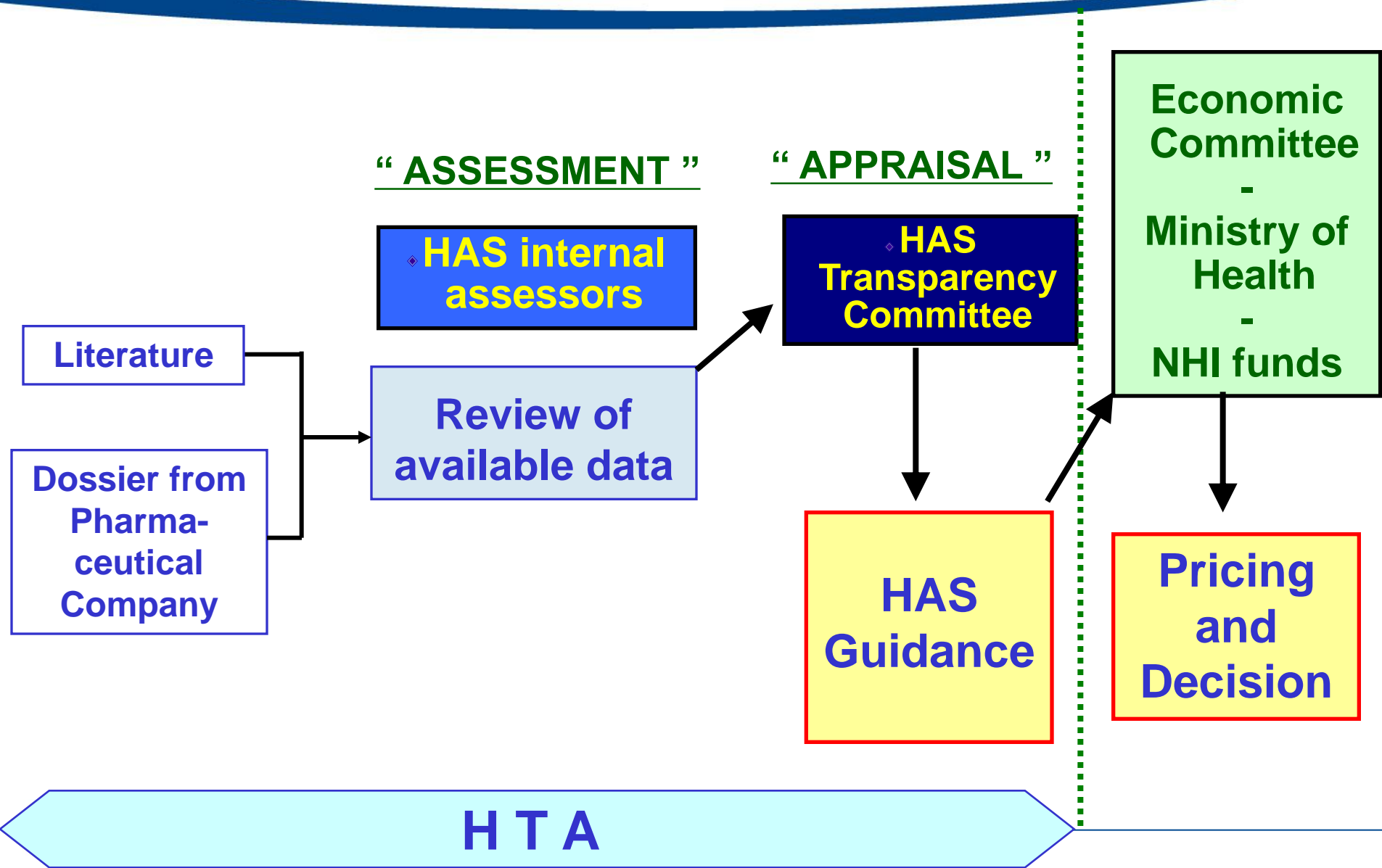
Article 15 of Cross Border Healthcare Directive

- The Union shall support and facilitate **cooperation** and the **exchange of scientific information** among Member States within a voluntary network connecting bodies responsible for HTA.
- Objectives of the network
 - support Member States in the provision of **information** on the **relative efficacy** as well as on the short- and **long-term effectiveness** when applicable, of health technologies and to enable an effective exchange of this information;
 - support the analysis of the **nature and type** of information that can be exchanged;
 - avoid duplication of assessments.

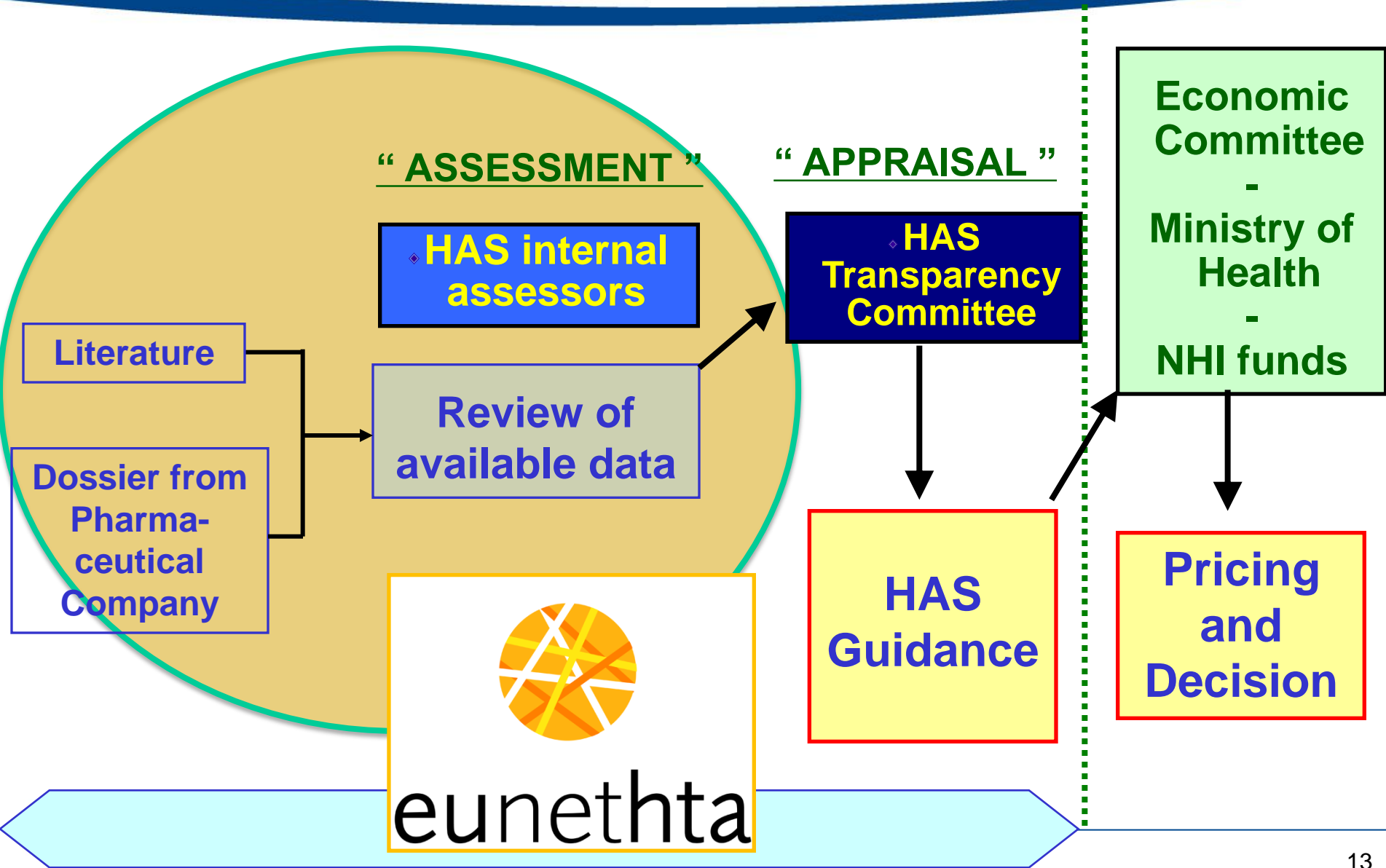
Future HTA network Article 15

- Measures adopted pursuant to this Article **shall not interfere** with Member States' competences in deciding on the implementation of HTA conclusions and **shall not harmonise** any laws or regulations of the Member States and **shall fully respect** the responsibilities of the Member States for the organisation and delivery of health services and medical care.

HTA, pricing and reimbursement in France



International cooperation on HTA





03

**What
cooperation?**

What cooperation?

- **Avoid duplication of work and reduce unjustified differences in HTA reports**
 - Do all the HTA bodies have the same data in hand?
 - Is the use of existing methodologies for HTA applied in an harmonised way?
- **Improve the appropriateness of the data**
 - Initial data production (technology development)
 - Additional data generation (post launch studies)

Avoid duplication of work and reduce unjustified differences in HTA report

- **Production of a common set of data to be taken into account for the local production of HTA reports:**
 - « Core HTA information »
- **Assessment methods: Methodological guidelines production**
 - Choice of comparator
 - Clinical endpoints
 - Composite endpoints
 - Surrogate endpoints
 - Direct and indirect comparisons
 - HRQoL
 - Safety
 - Internal validity
 - Applicability



ACTIVITIES

EUnetHTA Joint Action 2 (2012-15)

EUnetHTA Joint Action (2010-12)

JA WP1 - Coordination

JA WP2 - Dissemination

JA WP3 - Evaluation

JA WP4 - Core HTA

JA WP5 - Relative Effectiveness Assessment of Pharmaceuticals

JA WP6 - Information Management System

JA WP7 - New Technologies

JA WP8 - Strategy and Business Model Development

EUnetHTA Joint Action 2010-2012 Meetings

EUnetHTA Joint Action Stakeholder Involvement

EUnetHTA JA Public Consultations

[EUnetHTA startpage](#) / [Public](#) / [Activities](#) / [EUnetHTA Joint Action \(2010... / EUnetHTA JA Public Consulta...](#) / B. Public consultation of draft methodology guidelines for Relative Effectiveness Assessment of Pharmaceuticals

Public consultation of draft methodology guidelines for Relative Effectiveness Assessment of Pharmaceuticals

EUnetHTA is pleased to announce that as of today the second batch of draft methodology guidelines on direct and indirect comparisons, clinical endpoints, health related quality of life (HRQoL), safety and internal validity for Relative Effectiveness Assessment of Pharmaceuticals has entered the public consultation phase.

This consultation will take place between September 3 and October 31, 2012.

Objective

The primary objective of these methodology guidelines is to focus on methodological challenges that are encountered by HTA assessors while performing a rapid relative effectiveness assessment of pharmaceuticals.

In total, 9 guidelines on methodological issues are being produced by Work Package 5:

- Clinical endpoints;
- Composite endpoints;
- Surrogate endpoints;
- Safety;
- Health related quality of life (HRQoL);
- Criteria for the choice of the most appropriate comparator(s);

Appropriateness of data

- **Early Dialogue between HTA bodies and companies**
 - Scientific advice (SA) in place for a long time at regulatory agencies
 - Some HTA bodies recently implemented SA activities
 - Some joint/parallel Regulatory + HTA SA
- **Need for:**
 - Multi HTA early dialogue
 - Extension to non-drug technologies

Appropriateness of data (Cont.)

Early Dialogue

- **2 pilots of « multi HTA » early dialogue done (june 2012)**
 - With voluntary participation of EUnetHTA partners (Germany, UK, Austria, Belgium, Italy, Netherlands, France)
 - Coordinated by HAS (Mira Pavlovic, Anne Gourvil)
 - With support from European Commission (DG SANCO)
- **Practical aspects:**
 - Letter of intent: Eligibility?
 - Briefing book: Summary of available data, description of draft development plan, list of questions...
 - Meeting between sponsor and HTA bodies

Appropriateness of data (Cont.)

Disease specific guidelines

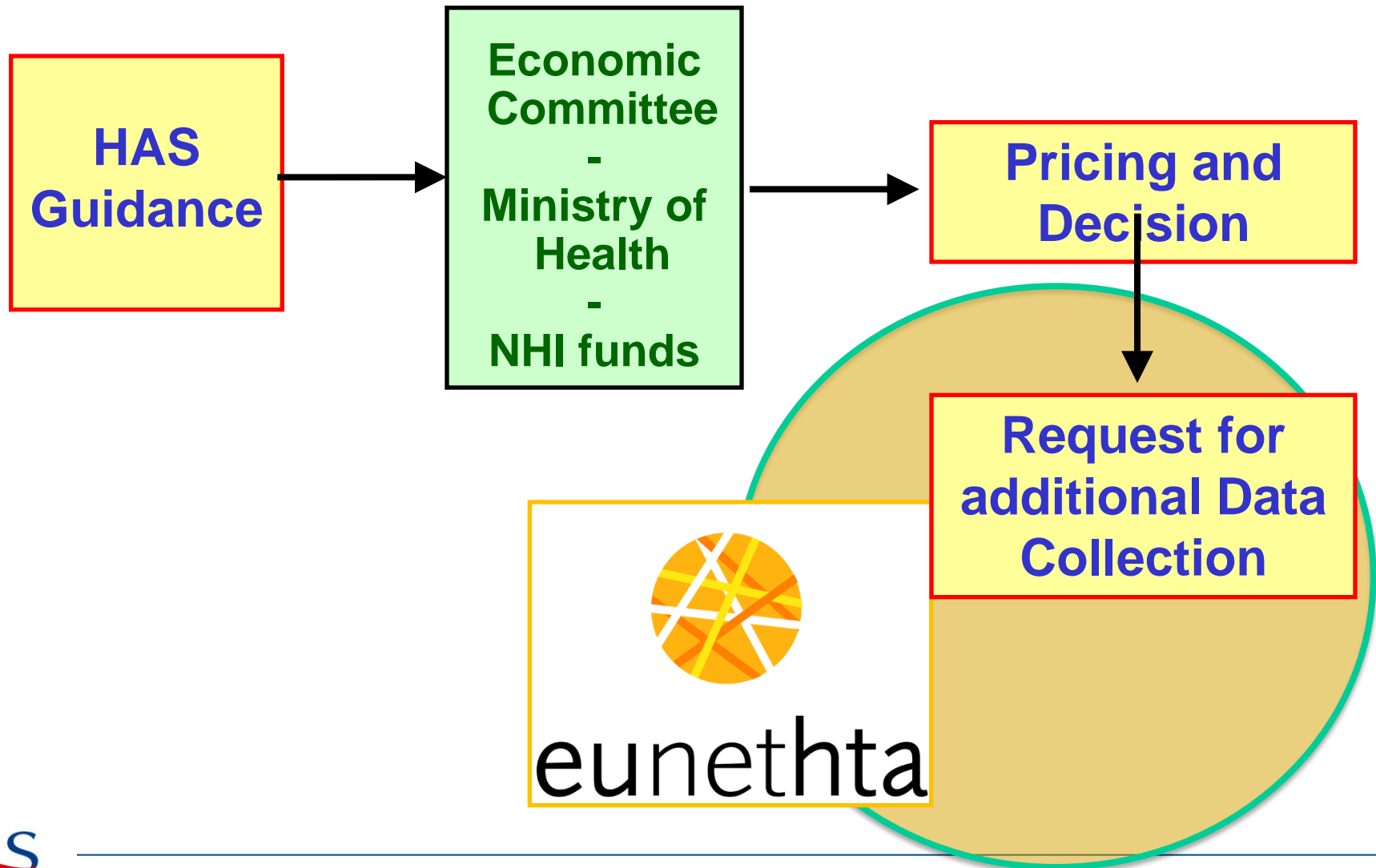
- Currently: ongoing pilot project on Alzheimer Disease
Green Park Collaborative (CMTP – HTAi)
- Starting October 2012:
Disease specific guidelines part of the EUnetHTA Joint Action 2 (Work Package7)

Appropriateness of data (Cont.)

Additional data collection: EUnetHTA objectives

- Definition of **criteria** to select new technologies in need of further evidence
- **database** (EVIDENT) to share information & facilitate collaboration on additional evidence generation
- Joint Action 2 : For some technologies, cooperation of several HTA bodies to define a common research question and a « **common core protocol** »
- EMA – EUnetHTA cooperation

International cooperation on HTA



Cooperation at different stages

- **Early stage :**
 - Early dialogue /Scientific advice
- **At the time of initial assessment/appraisal**
 - Common 'core' set of data
 - Shared methodological guidelines
- **After product launch: additional data collection**
 - From complete partition to active cooperation
 - Achieved: Criteria to select technologies, IT tools to communicate between HTA bodies
 - Next step: cooperation to define common research question, common core protocol

At all stages: Cooperation with EMA +++

Conclusion

- **Value appraisal not in the mandate of the European network (current joint action, future permanent network) of HTA bodies in Europe**
- **Significant actions are however performed to reduce unjustified differences between local HTA reports/guidance**
- **Early Dialogue is a unique opportunity for industry to appreciate the common and specific views of HTA bodies with regard to clinical and economic data to be produced during development**