HAUTE AUTORITÉ DE SANTÉ

Additional Data Collection for Drugs in Europe
HTA perspective

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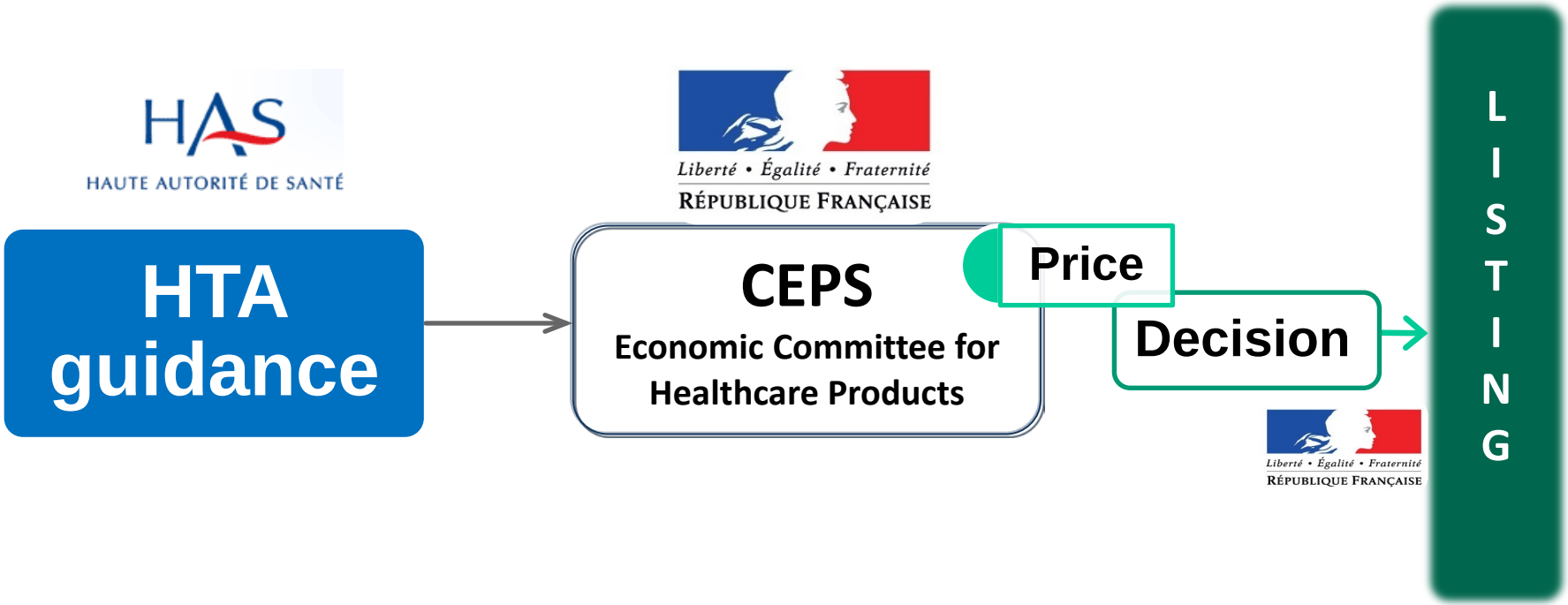
The situation in France: HTA on New Drug Reimbursement and Pricing



HAS Guidance Content for a new drug

1. **Eligibility to reimbursement (SMR)**
   - Full indication ***or*** restricted to situations or subpopulations
2. **Assessment of clinical added value (ASMR)**
   - What is the clinical added value and for what population?
3. **Target population**
   - Quantitative estimate
4. **Uncertainty**
   - and need for additional data collection
5. **Recommendations**
   - for use in clinical practice

Request for Additional Data Collection (ADC) How does it work?

- **Request expressed by HAS, CEPS, Ministry**
- **Included in the Contract signed between Pricing committee and the company**
- **The company has to :**
  - Draft a study protocol
  - Submit it to HAS for approval
  - Implement and conduct the study
  - Submit data to HAS and MoH.
- **Data are taken into account at the time of reassessment.**
  - Summary of the results published with HTA report

Requests for ADC 2004 – 2011 - Drugs

- **815 appraisals made for a new product or a new indication**
- **ADC request: 165 /815 (20.2%)**
- **Questions :**
  - Conditions of prescription / use
  - Benefit for patients (mortality morbidity QoL)
  - Impact on healthcare organisation
  - Others (to come: Economic parameters)
- **Data taken into account at the time of drug re-assessment (after at most 5yrs)**

HTA and request for Additional data collection accross Europe

Heterogeneous situation:

- **Recommendation / request**
  - Recommendation or request for ADC may be present or not in HTA reports, depeding on countries/institutions
  - In general terms or as a detailed question to be answered
- **Performance Based Risk Sharing Arrangements (PBRSAs)**
  - Are specific to national contexts and very unevenly developed
- **Conduct of the study may be done by companies, by public bodies, academia...**
- **Funding mechanism variable and not always available**

Bridging activities and cooperation between HTA bodies in Europe

Before the set up of EUnetHTA:

- **No structured cooperation on the field of Additional Data Collection**
- **No organised information flow between HTA bodies**
- **National ADC done (or not) in a non-coordinated way.**
- **Few, if any, possibility to pool the data from the different national studies**

The EUnetHTA actions in the field of Additional Data Collection

The role of EUnetHTA
Achievements of the EUnetHTA JA 1
1) The EVIDENT Database

Description

The EVIDENT Database enables sharing early information on evidence gaps identified during the production of HTA reports and consequent recommendations / requests for additional data collection.

It also contains information on reimbursement/ coverage and assessment status of promising technologies in Europe.

Purpose

To reduce redundancy, promote generation of further evidence and facilitate European collaboration in the domain.

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2) Additional Evidence Generation: **Selection/prioritization criteria**

Primary criteria: eligibility for ADC?

1. Did you identify any critical evidence gaps during HTA? (yes, no)

2. Is the research question explicitly defined? (yes, no)

3. Is ADC feasible (especially in terms of timeframe, type of study, population and costs)? (yes, no)

4. Is there a planned/ongoing similar study elsewhere?

a) Yes, but there is an additional value of performing this one too (yes, no).

b) No, thus this one is really necessary (yes).

5. Is there an added value of additional data for the subsequent HTA and decision making? (yes, no)

One 'no' makes the technology not eligible!

Secondary criteria: further selection and prioritization

1. Burden of target disease (mortality, morbidity prevalence, incidence, DALYs, QALYs)

2. Expected benefit of the technology (on the burden of disease/on the management of disease/economical, organisational, social, ethical benefit)

3. Potential of the technology to cover unmet health care needs or to substantially improve the healthcare system compared to existing alternatives

4. Importance of ADC for confirming expected benefit and/or monitoring/ optimizing the conditions of use.

EUnetHTA Joint Action 2 (2012-2015) Planned deliverables

- Recommendations on the implementation of sustainable European network for HTA
- Full Core HTAs
- Pilot rapid assessments
- Methodological guidelines and Templates to support production of core HTA information and rapid assessments
- **Guidelines and pilots to improve quality and adequacy of initial and additional evidence generation**
- Upgraded and updated application package of HTA Core Model
- Report on yearly training courses on EUnetHTA tools and methodology
- Report on evaluation of project completion including assessment of impact on secondary users of HTA information

EUnetHTA Joint Action 2 (2012-2015) Planned deliverables

Additional data collection - Deliverables

- Ongoing survey on ADC capacities
- How to best define research question and appropriate methodology (common core protocol)
- Conduct of pilots

Cooperation with EMA and ENCePP

- European Network of Centers of Pharmacoepidemiology and Pharmacovigilance
- How to coordinate request for post-launch data collection (PAES, PASS, HTA requests)

HTA-regulators-academia interactions

- Coordination and collaboration between HTA, regulators, pharmacoepidemiologists needed:
  - to avoid to conduct multiple, fragmented studies
  - to ensure optimal quality of ADC to produce adequate data that are produced in most efficient way
  - And will satisfy the needs of the various actors

EUnetHTA Joint Action 2 (2012-2015) Planned deliverables

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Thank you for your attention

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