Health Technologies Economic Evaluation

JL Harousseau

Chairman

Haute Autorité de Santé (HAS)

The French healthcare system

1. National Health Insurance (NHI)

- Statutory, coverage > 90% of the population
- Three major funds: salarees, rural workers, self-employed
- Universal Medical Coverage (CMU) since 2000: for uninsured patients and supplementary coverage under threshold income

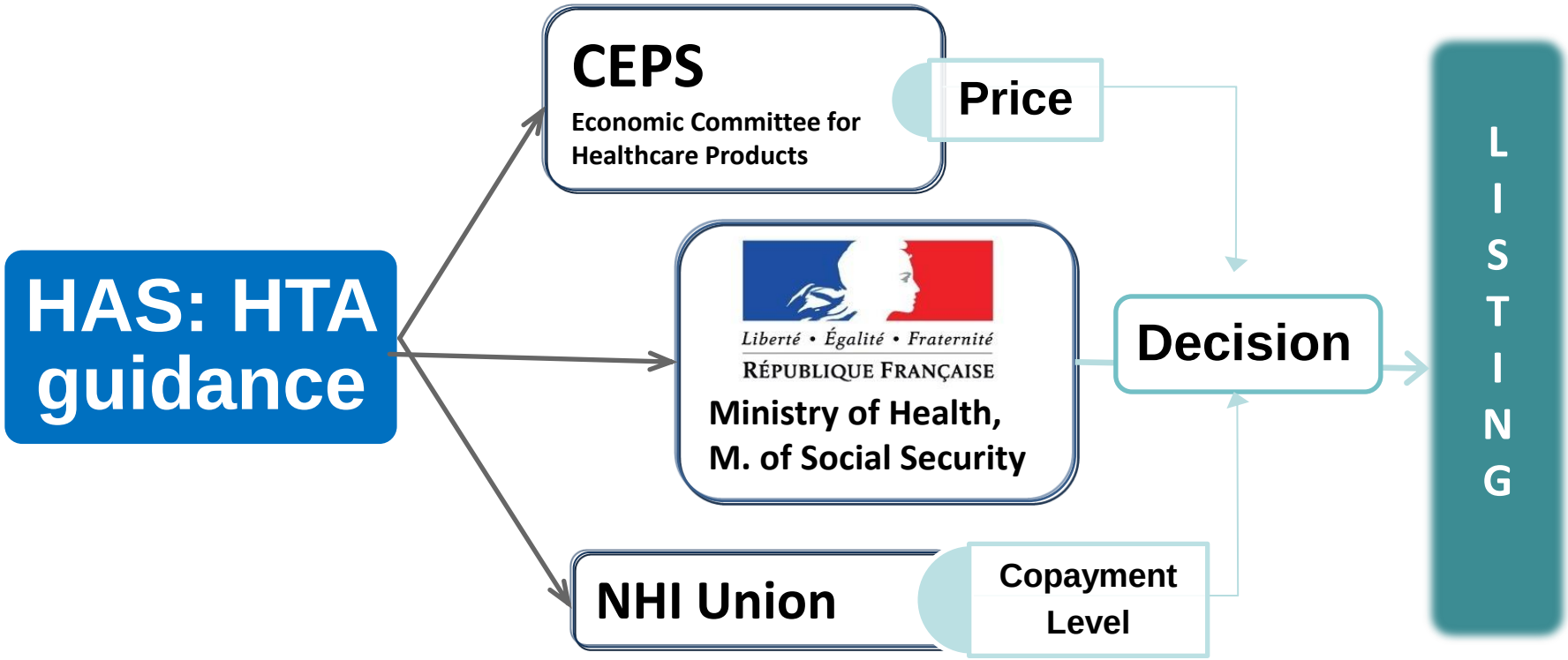
2. Supplementary Health Insurance:

- 92 percent of the population subscribe to supplementary health insurance

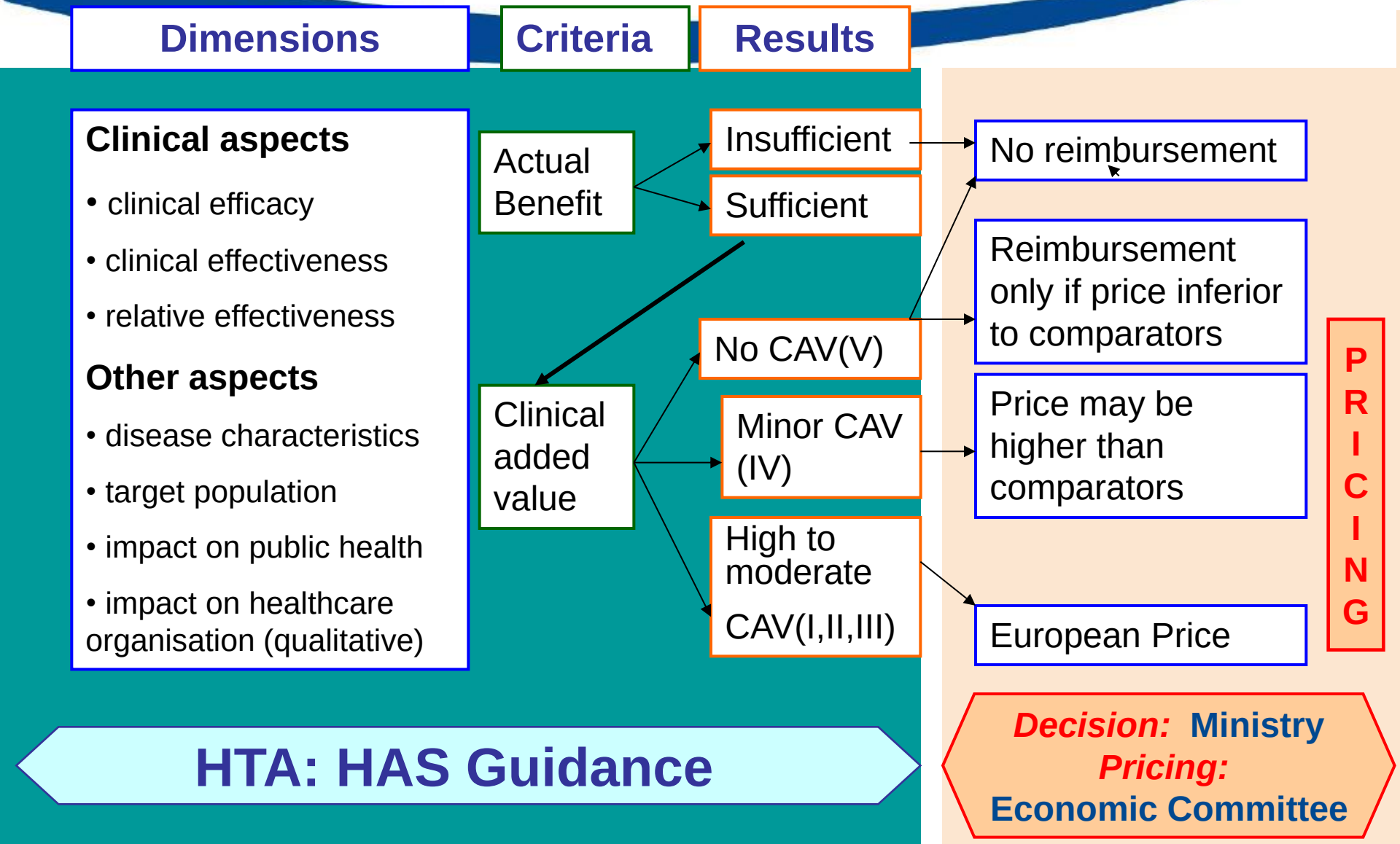
3. Which medical services are covered ?

- Hospital care, ambulatory care, prescription drugs
- For prescription drugs:Coinsurance level depends on the therapeutic value. 100% coverage by NHI in 29 chronic diseases

HTA in France
Reimbursement and Pricing
The actors



Initial listing: From HAS guidance to CEPS pricing



ACTUAL BENEFIT (SMR): reimbursement and copayment level

SMR	Level of reimbursement by NHI
Important	65%
moderate	30%
minimal	15%
insufficient	NO REIMBURSEMENT

Medical Benefit (SMR)

Niveau de SMR	Nombre de SMR N (%)
Important	**177 (71.7%)**
Moderate	**21 (8.5%)**
Minimal	**21 (8.5%)**
Insufficient	**27 (10.9%)**
ND	**1 (0.4%)**
TOTAL	**247**

Si un médicament a plusieurs indications avec le même SMR, celui-ci n'est comptabilisé qu'une fois.
S'il possède des SMR différents, ils sont comptabilisés une fois dans chaque catégorie concernée. En 2012, 17 avis ont comporté 2 SMR différents et 7 ont comporté 3 SMR différents ce qui explique que le nombre de SMR formulés (247) soit plus élevé que le nombre d'avis rendus (216).

Rules governing price setting

1. Primary considerations when setting prices:

- **added clinical benefit** (ASMR),
- prices of **comparators**,
- forecast **sales volumes** (clawback payments in case of overshooting)

2. Link between ASMR and price

- drugs that provide **no added clinical benefit** (ASMR 5) as assessed by HAS and **no savings** on treatment costs **cannot be reimbursed**
- Drugs with ASMR 1-3 : the price is not inferior to the lowest price in 4 European countries

Rules governing price setting

1. **Spending objective: ONDAM**
   - Parliament adopts every year a national health spending objective (ONDAM),
   - indicative, not compulsory.
2. **CEPS' s task is to obtain the most advantageous price and financial conditions for the NHI system,**
3. **whilst taking into consideration**
   - both the pharmaceutical market as a whole
   - and the limitations of the ONDAM budget,
   - as well as public health needs
   - and the obligation to treat all the companies equally.

Why is France introducing Medico-economic assessment of drugs and devices ?

1. **The economic context**

2. **Increasing costs of expensive therapies without clear clinical superiority**

3. **Very high cost of new therapies (including targeted therapies , orphan drugs)**

4. **At all levels of the health-care system**

- health technologies (reimbursed drugs: <20% of healthcare costs)

- appropriateness of medical choices and practices

- organization of patient pathway

The objectives of medico-economic assessment

1. Not just for reducing health-care expenses
2. Not just for indicating the costs
3. But to inform decision makers on possible disproportions between incremental costs and incremental effectiveness
4. And provide them with a scientific and accurate guidance

The principles of medico-economic assessment

1. **Cost-effectiveness assessment**
2. **Comparative assessment**
   - **Qalys used as a tool for comparing drugs**
3. **Incremental Cost-Effectiveness Ratio (ICER) Euros per Qaly at different prices**
4. **No predefined ICER threshold**

   No consensus on the use of thresholds
   - **How to define threshold ?**
   - **One or more thresholds ?**

Medico-economic Assessment in France

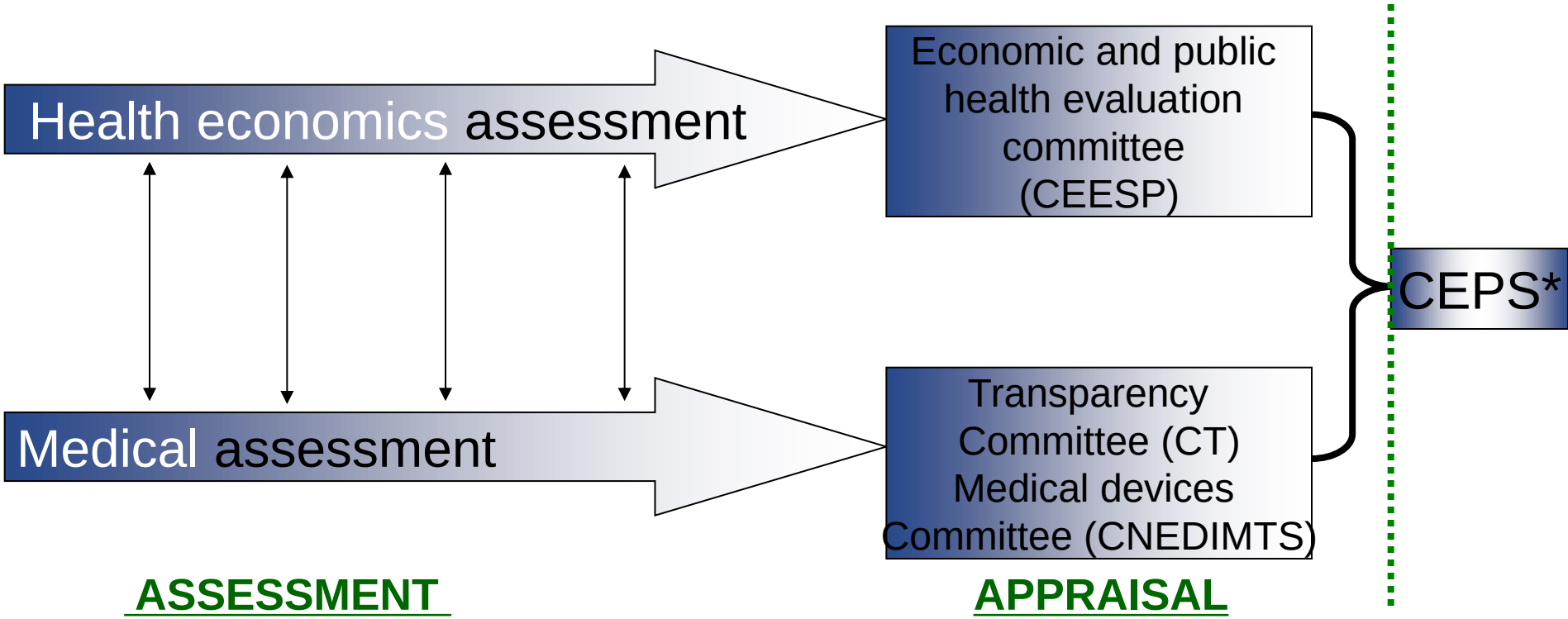
1. New Law (PLFSS 2012) and Decree (Oct 2012) to strengthen HAS' role in documenting the collective added value of technologies
2. When ?
   - first listing or reevaluation (relisting)
3. Which products ?
   - Drugs and medical devices
   - Innovations: ASMR I to III claimed by the company

   and - Significant impact on health care expenses (health care organization, price, professionnal practices) 20 M Euros /year at 2 years
4. How ?
   - Based on data provided by the company

HAS

Coordinated assessment/appraisal

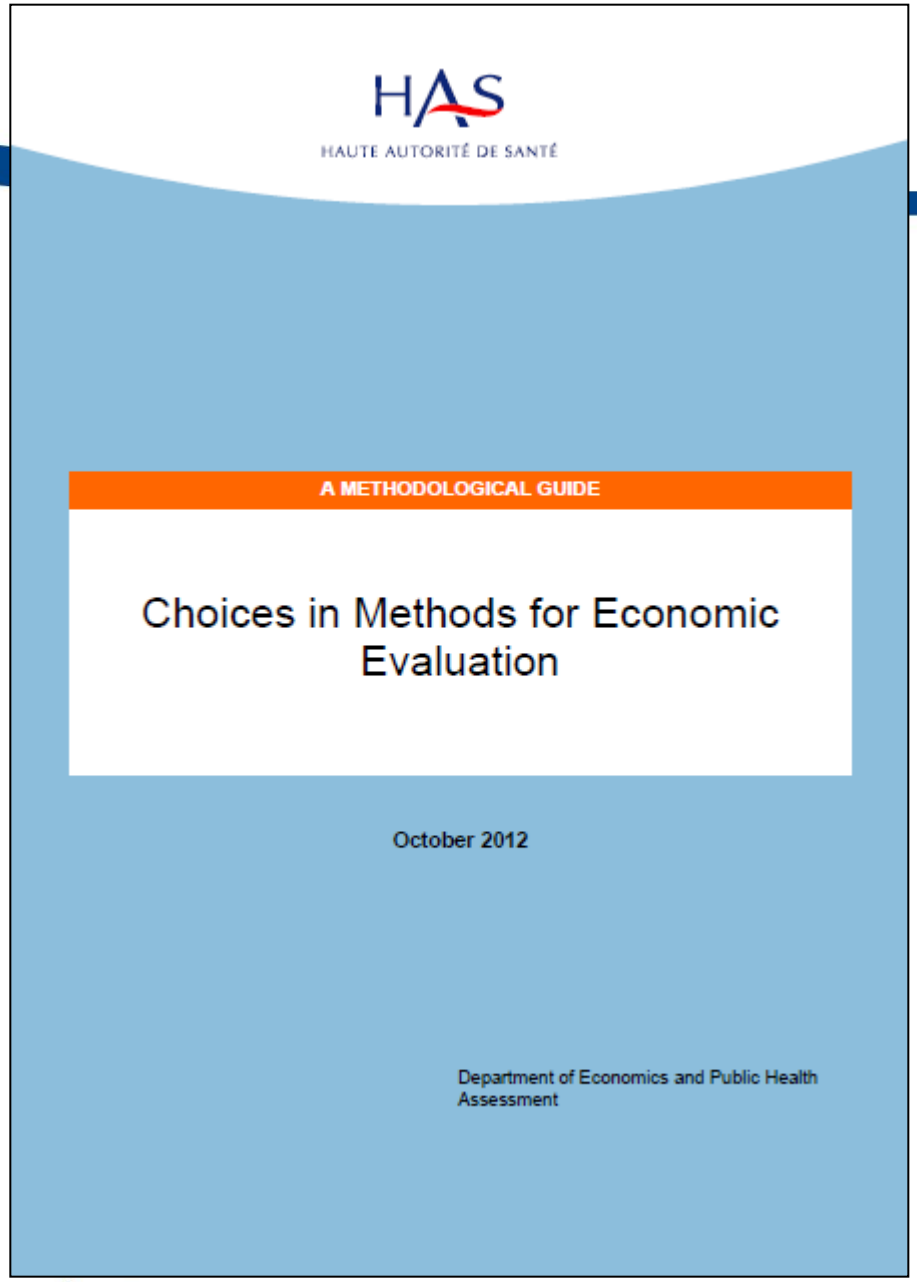
To provide the pricing committee (CEPS) with an assessment of clinical added value (individual benefit) and an economic opinion (collective benefit)



Economic opinion process (90 days)

(National early dialogue meeting)

1. Submission
2. Administrative compliance
3. Scientific/methodological compliance
4. Internal analysis + economics sub-committee rapporteur
5. Complementary technical requests
6. Opinion draft
7. Economics sub-committee assessment
8. CEESP validation
9. Sending of the economic opinion to the company
10. Hearing (phase contradictoire)
11. Publication of the final opinion



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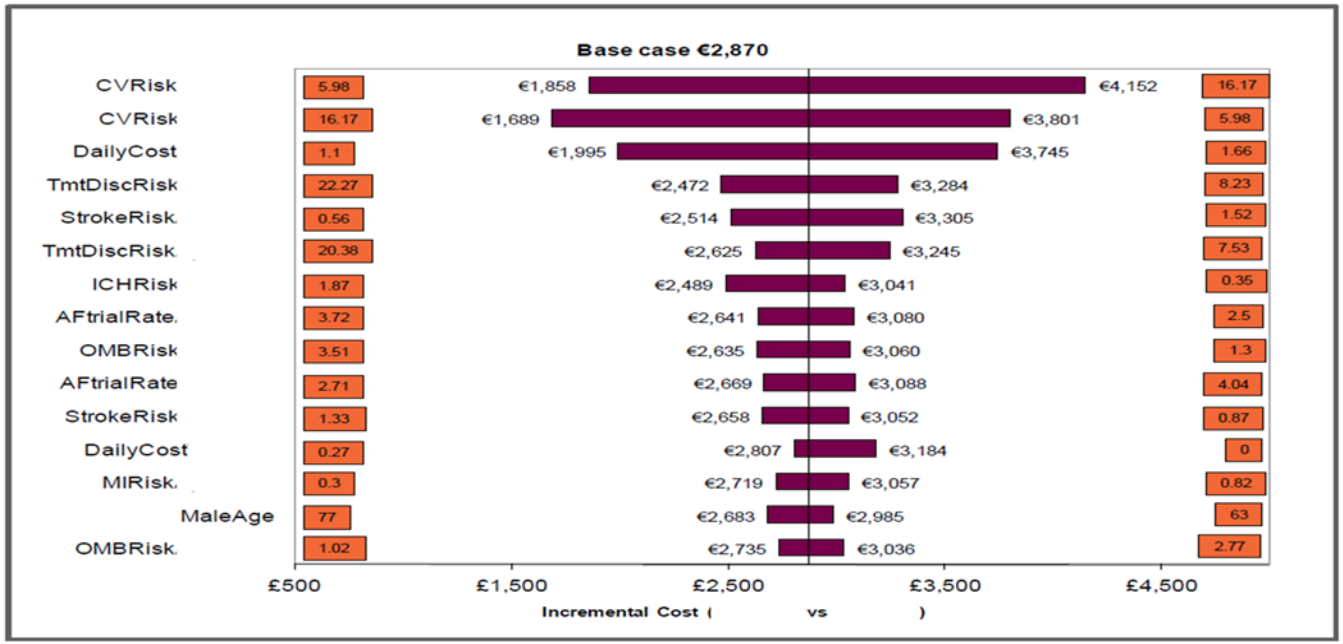
Content of the economic opinion

- **Administrative completeness of the submission**
- **Compliance with the HAS guidelines for economic evaluation**
- **ICER (cost-effectiveness or cost-utility)**
- **Assessment on the robustness of the ICER**
- **Potential need for additional data for reassessment within 5 years**
  - to verify ICER in real world

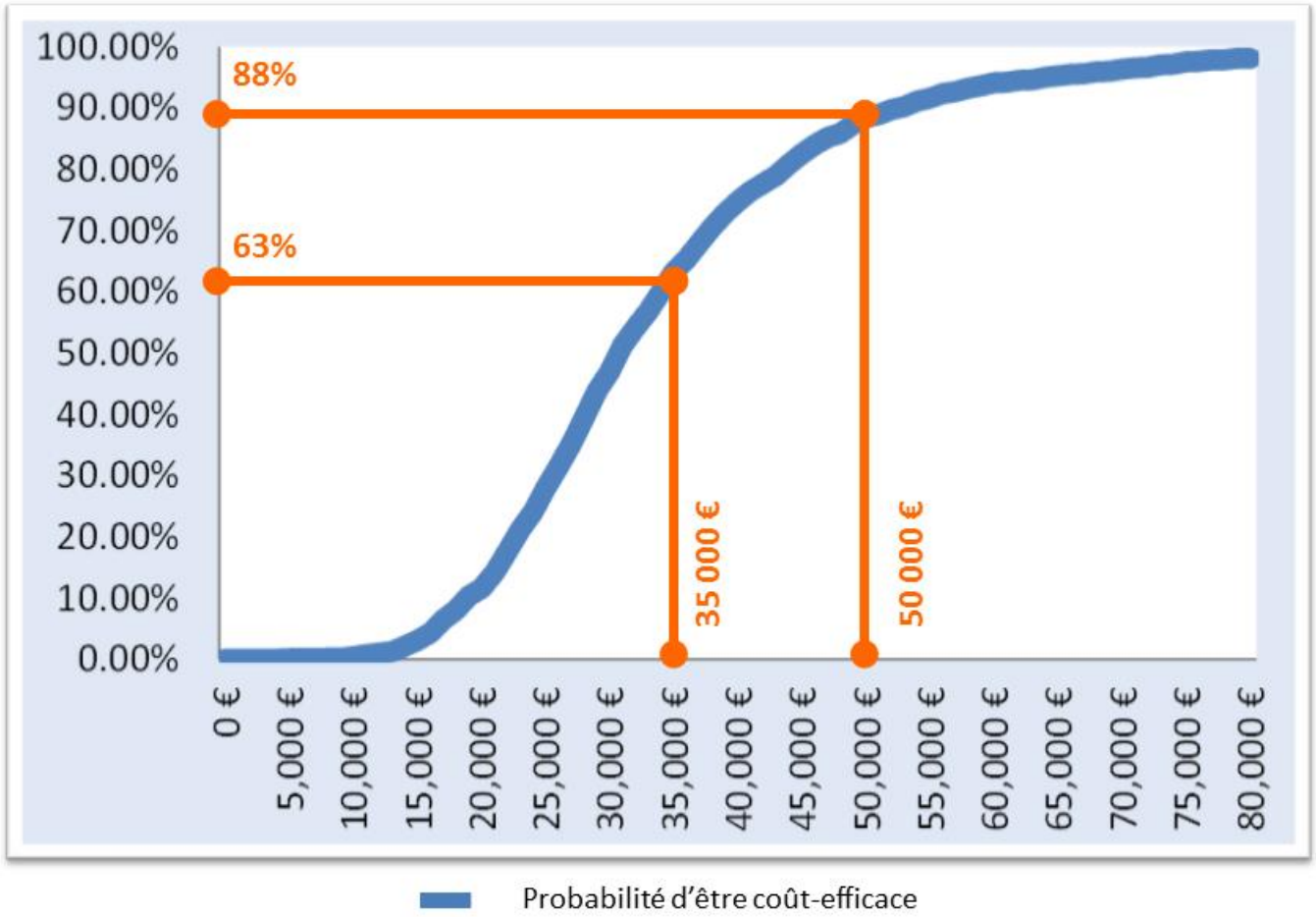
Univariate Sensitivity Analysis

This analysis defines the parameters which have the most important impact on ICER

Tornado Diagram Illustrating Results from Univariate Sensitivity Analysis for Incremental Costs



Acceptability curve



Preliminary Experience (September 2014)

Médicaments : 39

Eligibles à l'évaluation médico-éco : 20

Non éligible à l'évaluation médico-éco : 19

Dispositifs médicaux : 19

Eligibles à l'évaluation médico-éco : 1

Non éligible à l'évaluation médico-éco : 18

CEESP Opinions by September 2014

Number of opinions: 13

Compliance with HAS methodological guidelines

- 5 opinions with major limitations
- 6 opinions with important limitations
- 1 opinion with minor limitations

ICER results

- < 30 000 €/QALY: 3 opinions
- > 100 000 €/QALY: 2 opinions
- Dominant: 1 opinion

Drugs and diseases

- **4 cancer drugs:**
  - 1 breast cancer : Kadcyla® (trastuzumab emtansine)
  - 1 colorectal cancer: Vectibix® (panitumumab)
  - 1 prostate cancer : Xofigo® (radium 223 dichloride)
  - 1 chronic lymphoid leukemia : Gazyvaro® (obinituzumab) *
- **3 antiviral drugs**
  - 2 HCV : Sovaldi® (sofosbuvir), Olysio® (simeprevir)
  - 1 HIV : Tivicay® (dolutegravir)
- **2 multiple sclerosis drugs**
  - Lemtrada® (alemtuzumab)
  - Tecfidera® (dimethyl fumarate)

Drugs and diseases (cont'd)

- **3 vaccines**
  - 2 rotavirus: Rotateq®, Rotarix®
  - 1 zona et post-herpetic neuralgia: Zostavax®

- **8 other diseases**
  - Opsumit® (macitentan)
  - Adempas® (riociguat)
  - Nplate® (romiplostin)
  - Esbriet® (pirfenidone)
  - Defitelio® (defibrotide)
  - Entyvio® (vedolizumab)
  - Xolair® (omalizumab)
  - Botox® (botulinic toxin type A)

Questions

1) No threshold : how CEPS uses this information for pricing negotiations ?
2) The « Sovaldi case » : acceptable ICER but huge budget impact
3) HE used for pricing not for reimbursement
4) Publication (only after CEPS decision)

Conclusion

1. Complex system with 3 parameters (SMR, ASMR,CE)
2. HE assessment is used for pricing not for reimbursement
3. HE relies on CE not on the budgetary impact
4. HAS'proposal

   - only one (comparative) clinical assessement (REA) for the individual benefit

   - HE assessment for the collective impact