

**Medico-economic Assessment
Of Drugs /Medical Devices
In France**



**JL Harousseau
Chairman HAS**

Paris, March 18th

Update on the New HTA in France



JL Harousseau

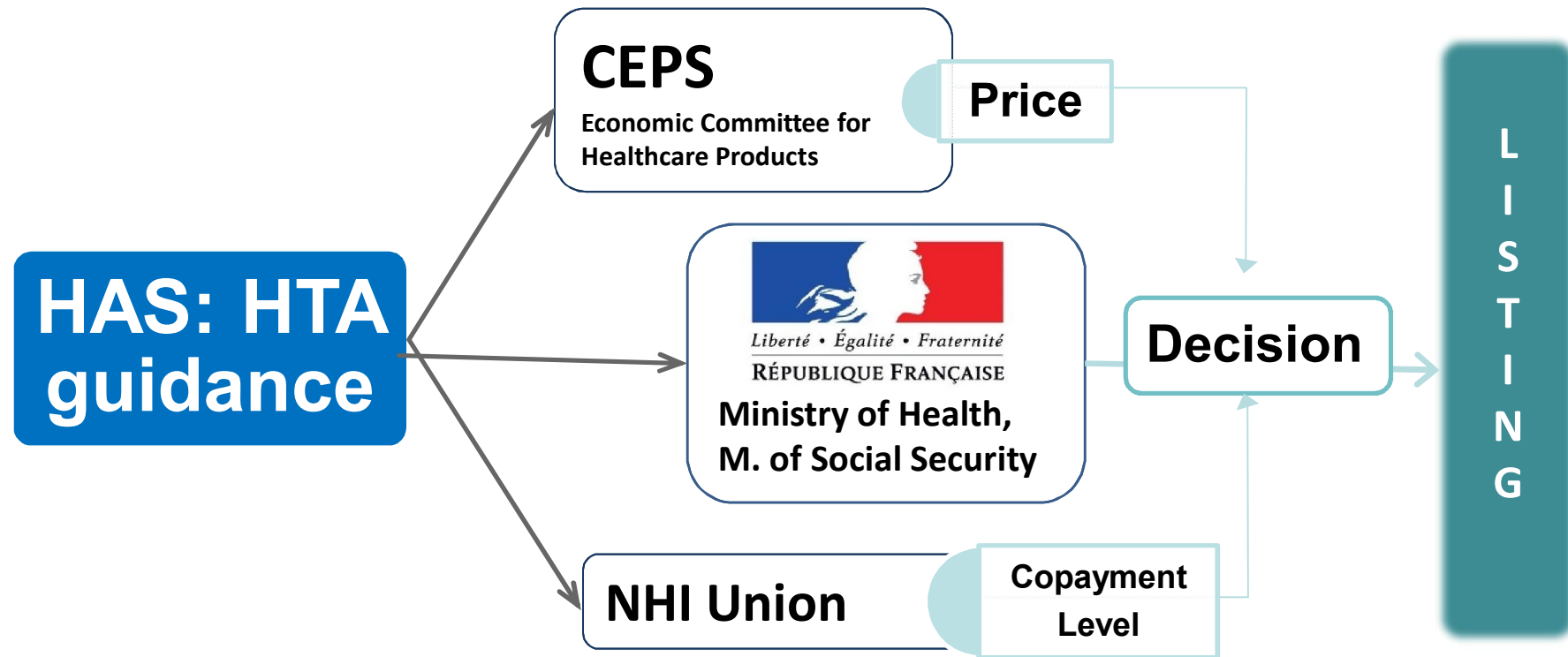
Chairman

Haute Autorité de Santé (HAS)

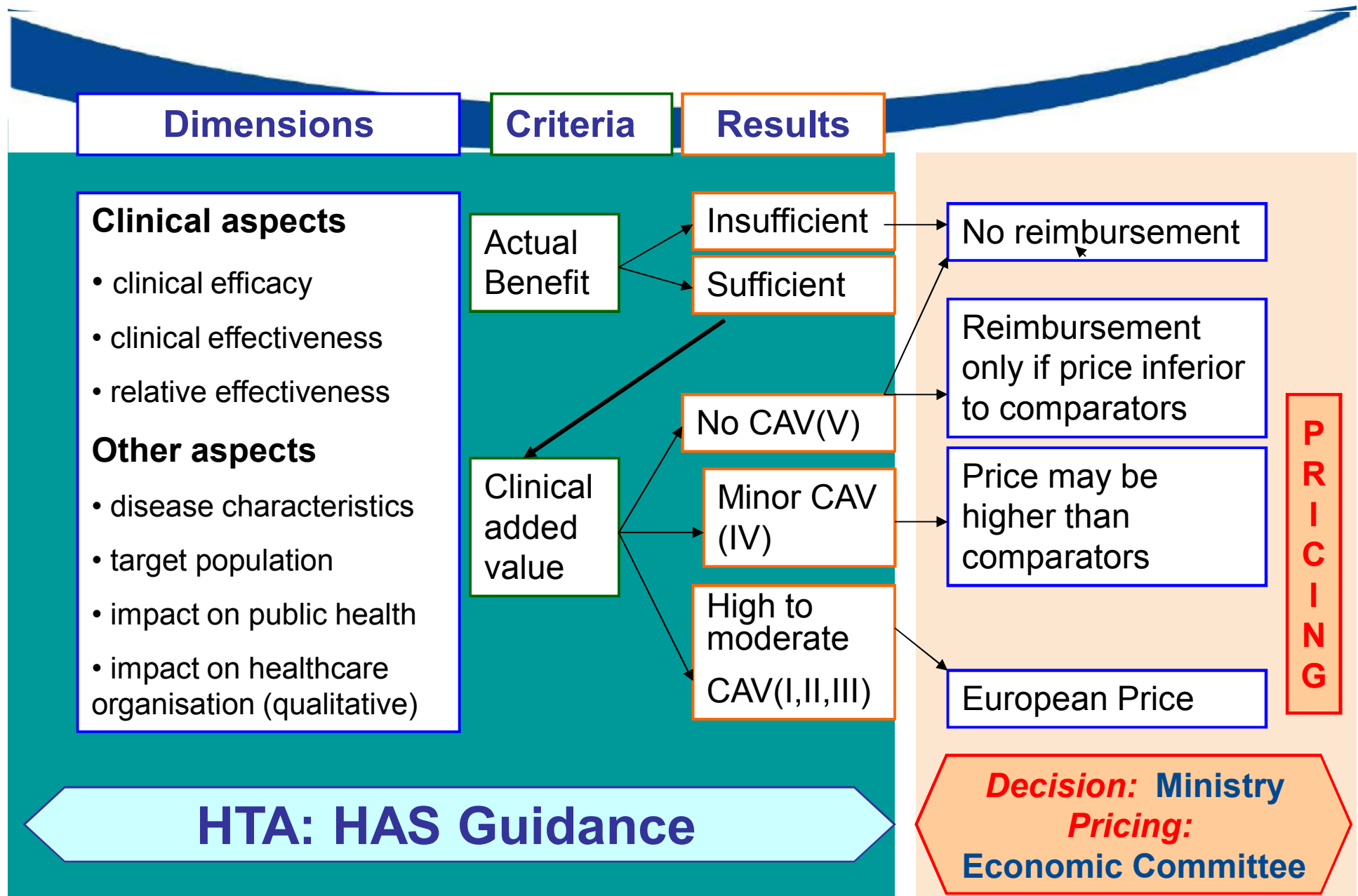
HTA in France

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%)
Insuffisant	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).

Insufficient SMR (2008-2012)

YEAR	% of SMRi First Registration
2008	2/38 soit 5,3%
2009	1/68 soit 1,5%
2010	9/61 soit 14,8%
2011	7/41 soit 17,1%
2012	6/60 soit 10 %

Dans ce tableau figurent les médicaments examinés en procédure complète dans le cadre d'une demande de première inscription pour lesquels toutes les indications ont reçu un SMR insuffisant, conduisant la Commission à donner un avis défavorable à l'inscription.

→ Auxquels s'ajoutent 11 retraits de demande avec SMR insuffisant en 2011, 5 en 2012 et 3 en 2013

Rules governing price setting

1. Primary considerations when setting prices:

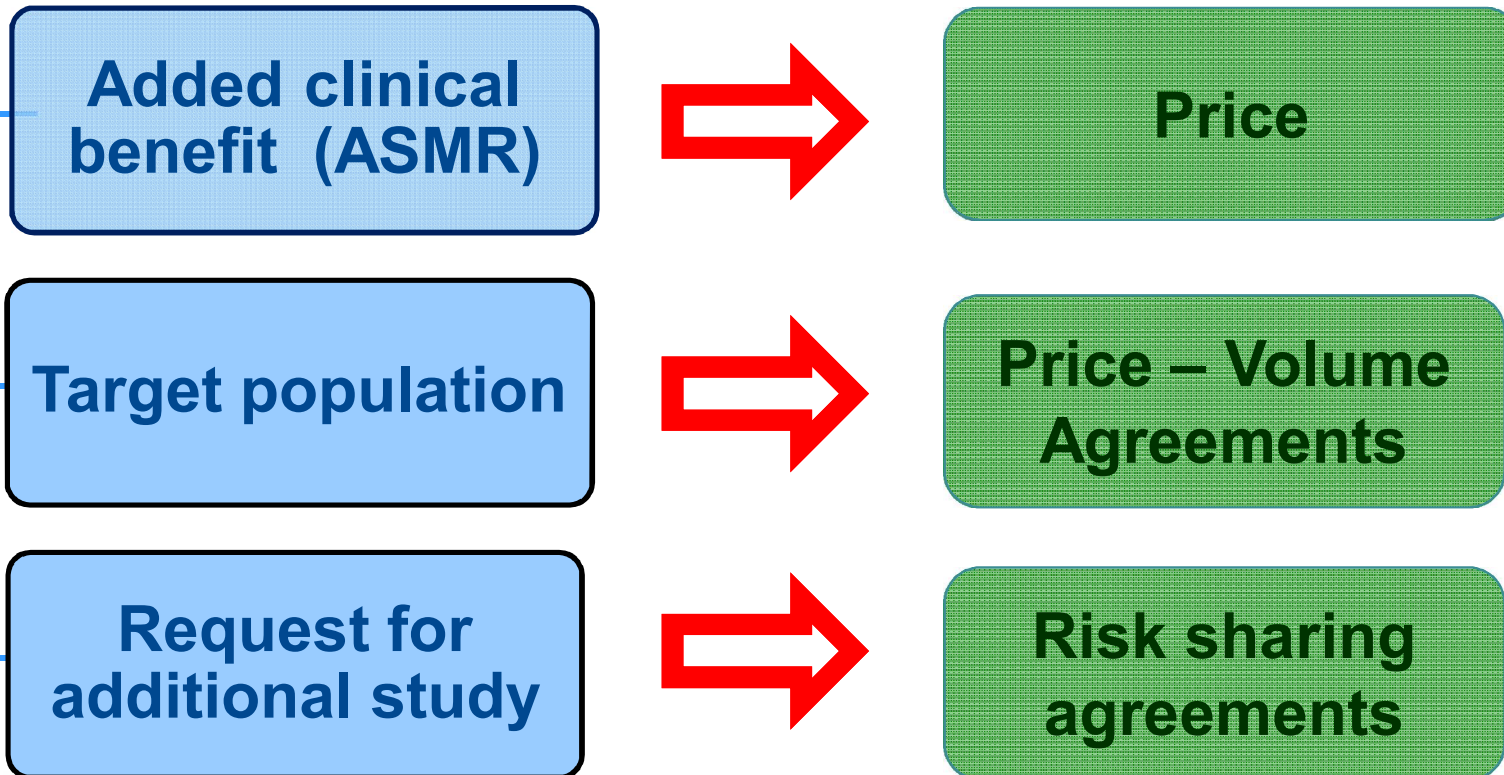
- added clinical benefit (ASMR),
- prices of comparators,
- forecast sales volumes (clawback payments in case of overshooting)

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

Link between guidance and decision

HAS Guidance



Clinical Added Value (ASMR) 2008 – 2012

Ces résultats concernent les demandes de premières inscriptions et les demandes d'extension d'indication examinées selon la procédure complète uniquement

ASMR	2008	2009	2010	2011	2012	2013 Janv/août
I	2	5	2	1	0	1
II	5	5	2	0	5	2
III	3	8	8	2	10	7
IV	17	20	20	20	19	11
V	48	65	46	29	46	26
Nombre total d'avis	75	100	85	58	80	49

Un même avis pouvant comporter plusieurs ASMR différentes et l'ASMR n'étant qualifiée que si le SMR est non insuffisant, ceci explique le décalage avec le nombre d'avis concernés

Rules governing price setting

1. Spending objective: ONDAM

- Parliament adopts every year a national health spending objective (ONDAM),
- indicative, not compulsory.

2. CEPS' 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

PRICES OF NEW DRUGS IN EUROPE

(51 drugs launched 2008-2012)

	France	Germany	Italy	Spain	UK
ASMR I/II/III	1.00	1.21	1.37	1.14	0.77
ASMR IV	1.00	1.02	0.95	1.09	0.96
ASMR V	1.00	1.41	1.05	1.13	1.07
Total	1.00	1.32	1.07	1.11	1.02

Control of Healthcare Costs

Objectives for both Liberal Practice and Hospital Costs

1. Until now few structural changes

2. Mostly - decrease of drug prices (CEPS)

- incentives for generics use (ticket modérateur :the part paid by the complementary insurance or the patient)

- control of transportation reimbursement

- decrease of fees for specialists (radiologists, biologists)

- incentives for GCP (ROSP)

RESULTS (CEPS Annual Report 2012)

- Global cost of reimbursed drugs 25.2 Bn E (-2.2%)

- Reduction of costs for the first time in France (+0.7 % in 2011)

- Liberal Practice – 3.4% (18.9 Bn)

- Hospîtal +1.7 % (6.3 Bn)

- In liberal practice

- Price Effect - 4.2 % (2000-2012 : - 22%)

- Volume effect -1.6%

- Structure Effect + 2.5 %

- Generic substitution: 70.7% vs 66.2 % in 2011 (39% of total sales vs 36%)

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

1. The economic context

The Economic Context

1. ONDAM (national objective for healthcare costs) (reimbursed by NHI)
 - Voted every year by the Parliament : 2.5 % in 2012, 2.8 % in 2013
Only 2.4 % in 2014
2. Decrease of health costs in the last 2 years
 - 2012 Total amount of health costs : 170 Bn Euros
 - - 1 Bn Euros compared to ONDAM
 - - 950 ME for liberal practice (+1.7%)
 - - 2013 Predicted costs 175 Bn E (expected 175.4 Bn E)
3. However deficit still increases due to incomes lower than expected (economic situation, unemployment)
 - For 2013 deficit might increase (1.8 Bn E)
4. In the general context of a poor economic growth
GDP 0% in 2012 , 0.3% in 2013

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**
Ex: + 6.4% for gliptins in 2012

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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)

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 will be 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

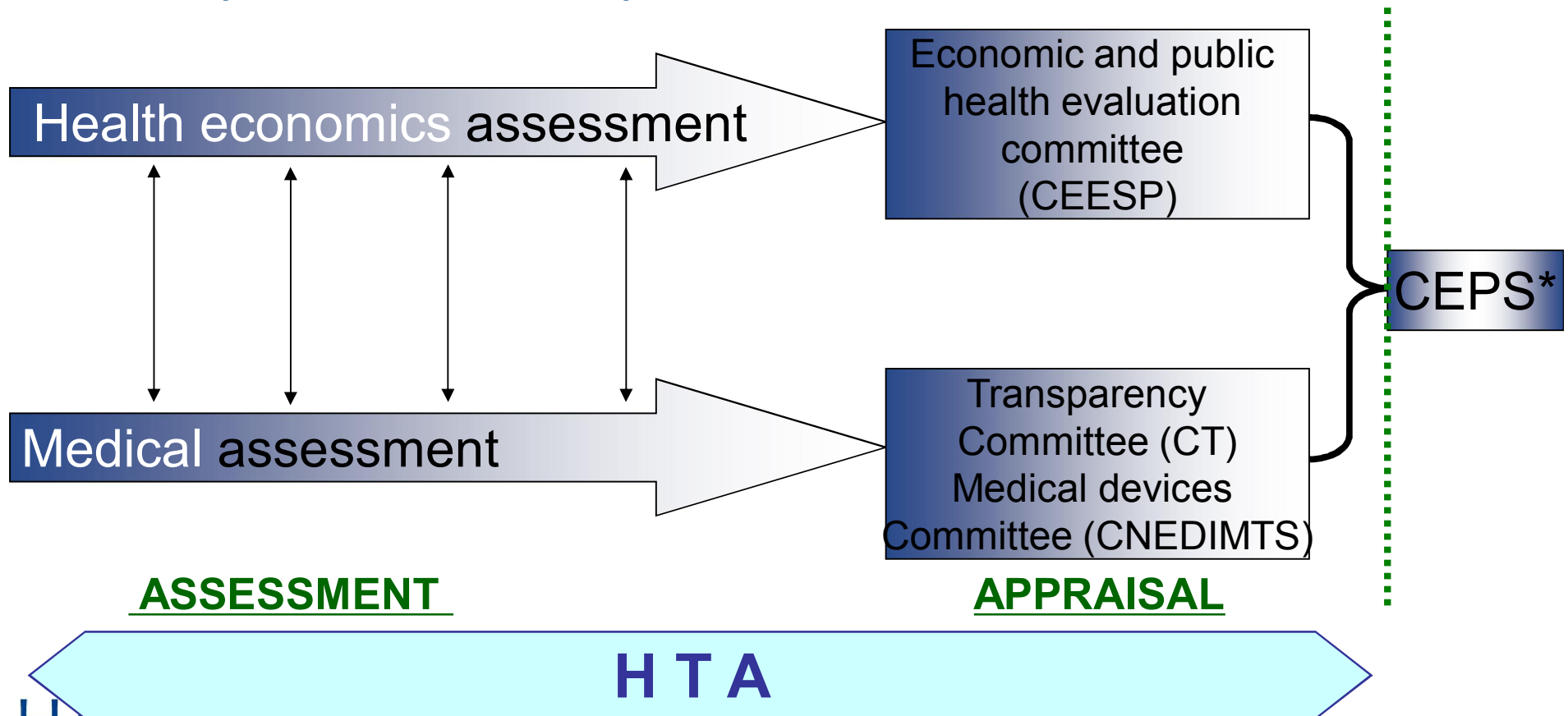
1. **New Law (PLFSS 2012) and Decree (Oct 2012) to strengthen HAS' role in documenting the collective added value of technologies**
2. **When ?**
 - **first listing or reevaluation (relisting)**
3. **Which products ?**
 - **Drugs and medical devices**
 - **Innovations: ASMR I to III claimed by the company**
 - and - **Significant impact on health care expenses (health care organization, price, professional practices)**
4. **How ?**
 - **Based on data provided by the company**
 - **Expected or observed efficiency (comparison with existing drugs or technologies)**

Practical details

- **Documentation of “significant impact” on health expenditure (>20 million €/year)**
 - To be provided by the company
 - To be checked by the HAS board of directors
- **Submission of the economic evaluation by the company**
 - Avis_efficiency@has-sante.fr
- **Early dialogue on request**
 - Avis_efficiency@has-sante.fr

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**

Template of the economic opinion

- **Economic Opinion of the CEESP**
- **Appendix 1 - Context of the request**
- **Appendix 2 - Critical analysis of economic evaluation**
- **Appendix 3 - Critical analysis of budgetary impact**
- **Appendix 4 - Synthesis of the critical analysis**
- **Appendix 5 - Exchange with companies**

Content of the economic opinion

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

A METHODOLOGICAL GUIDE

Choices in Methods for Economic Evaluation

October 2012

Department of Economics and Public Health
Assessment



www.has-sante.fr

How does the CEESP ends in this opinion ?

Two possible scenarios:

- **If the cost-effectiveness analysis does not comply with HAS guidelines:**
 - No ICER is provided
 - Major limitations of the analysis are highlighted
 - Efficiency of the technology is not demonstrated

How the CEESP ends in this opinion ?

- **If the cost-effectiveness analysis complies with the HAS guidelines:**
 - Minor methodological limitations of the analysis are highlighted
 - Uncertainty around the quantitative results and the parameters driving this uncertainty are described
 - The ICER for different prices are stated (without reference to any ICER threshold)
 - Other elements relevant to the interpretation of the results may be formulated

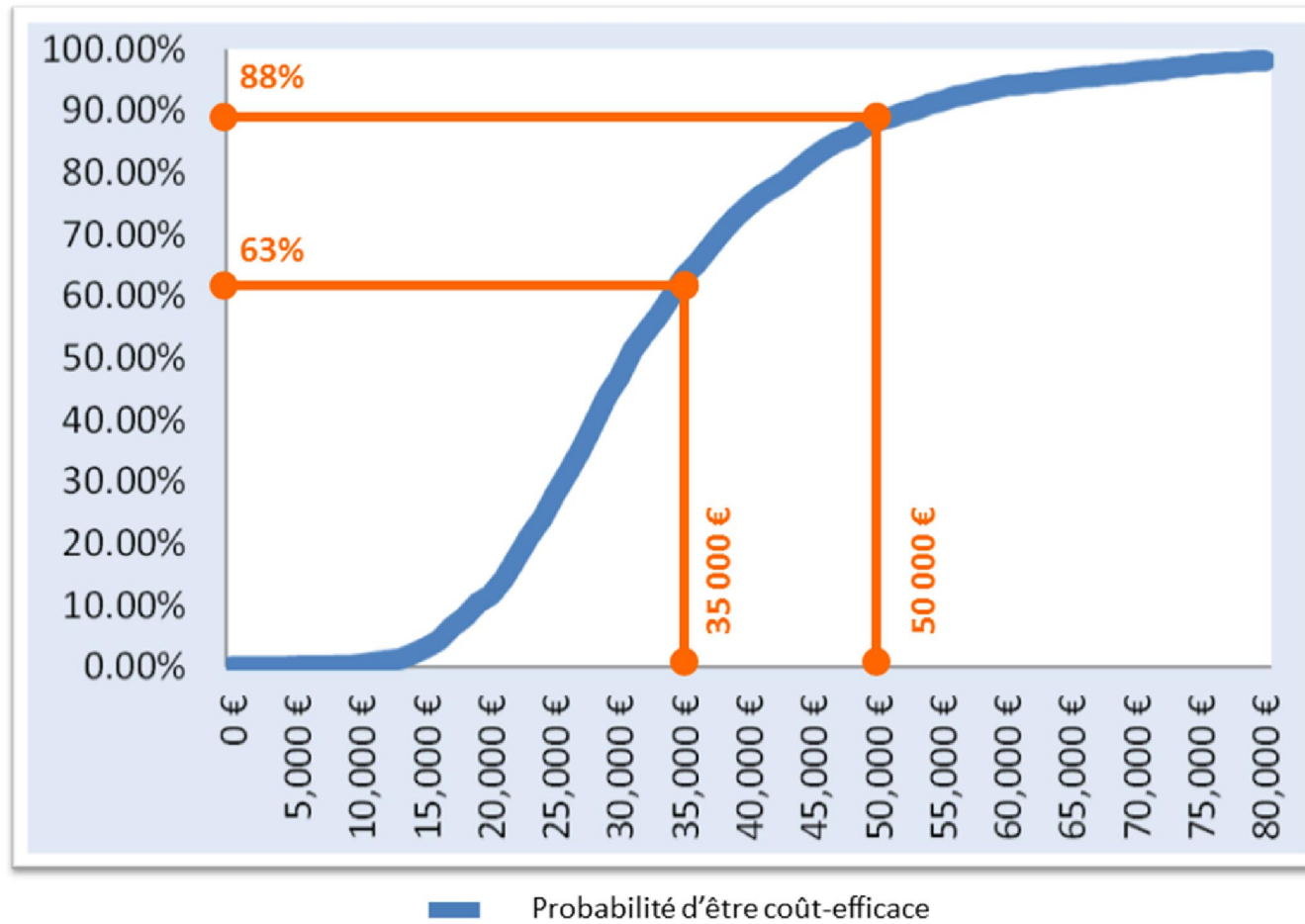
For more precisions

The conclusion presents several levels of probability in relation with the ICER

– An example :

“ Probabilistic sensitivity analysis realized by the company shows that at the price claimed of X €, in the population of the indication and on the whole life, in 80 % of the cases, the ICER is lower than approximately 50 000 € by QALY and that in 50 % of the cases, the ICER is lower than approximately 33 000 € by QALY.”

Acceptability curve



Since the decree comes into force

- **Economic evaluations are ongoing for the following drugs**
 - Defibrotide
 - Panitumumab
 - Radium Ra 223 dichloride
 - Trastuzumab emtansine
 - Alemtuzumab
 - Sofosbuvir
 - Herpes zoster vaccine