The role of economic evaluation in pricing and reimbursement of medicines in France

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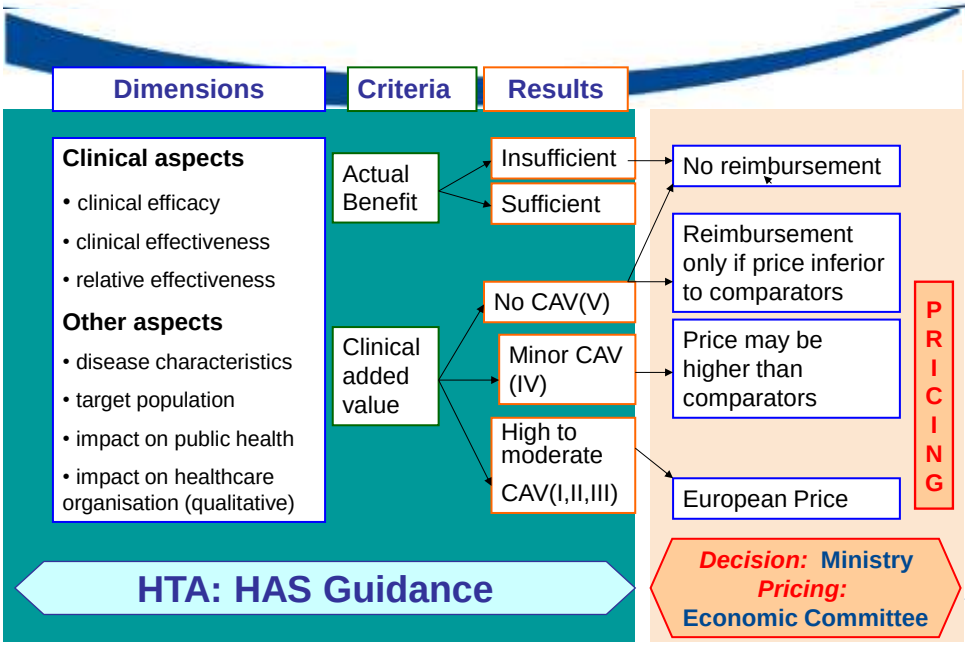
Initial listing: From HAS guidance to CEPS pricing



Criterion for reimbursement of medicines

Clinical benefit ('Service Médical Rendu', SMR)

– The National health Insurance defines the level of reimbursement according to the level of clinical benefit

SMR	Level of reimbursement
Important	65%
Moderate	30%
Mild	15%
Insufficient	Not included on the positive list

In chronic or severe diseases and in disabling conditions drugs are reimbursed at 100% (ALD list)

Criteria of price determination/negotiation of medicines (1)

Improvement in clinical benefit ('Amélioration du service médical rendu' ASMR)

- **ASMR reflects the relative clinical value of the medicine**
  - Does the medicine improve patients clinical situation, as compared to existing treatments?

- **Measure of the clinical added value**
  - Major: ASMR I
  - Important: ASMR II
  - Moderate: ASMR III
  - Minor: ASMR IV
  - No clinical improvement: ASMR V

Criteria of price determination/negotiation of medicines (2)

Consequences

- **ASMR I to III**
  - Price similar to that in other European countries (external reference pricing)
- **ASMR I to IV**
  - Possibility of price higher that the price of comparators
- **ASMR V**
  - The medicine can be listed provided that its price is lower than the price of the comparators or its use associated with cost savings

French medecines pricing system : main principles

Economic evaluation of medicines and medical devices in France (1)

- **Social Security Financing Act for 2008: HAS responsibilities in the area of economic evaluation (EE)**
  - Advice on the most efficient strategies for healthcare interventions, prescribing or patient management
- **HAS methodological guideline on EE**
  - Produced in October 2011 (English version October 2012)

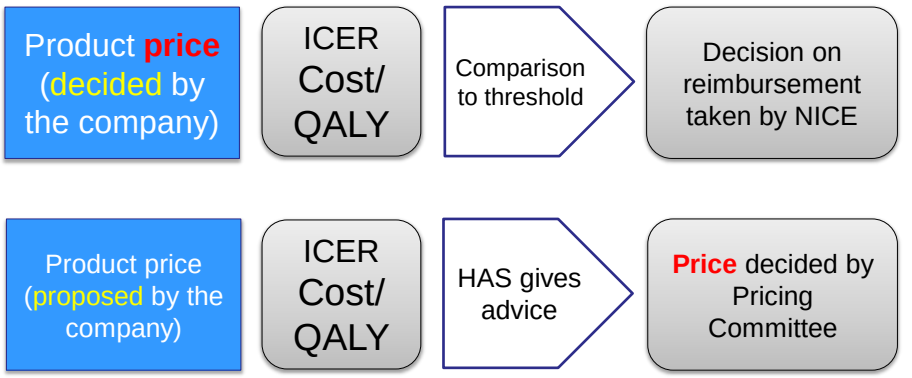
Economic evaluation of medicines and medical devices in France (2)

- **EE on medicines and medical devices required since 3/10/2013 (decree)**
  - To provide the pricing committee (CEPS) with an economic opinion for medical innovations claimed by manufacturers
- **Criteria for EE**
  - Improvement in clinical benefit ("ASMR/ASA") of level I (major) to III (moderate)

AND

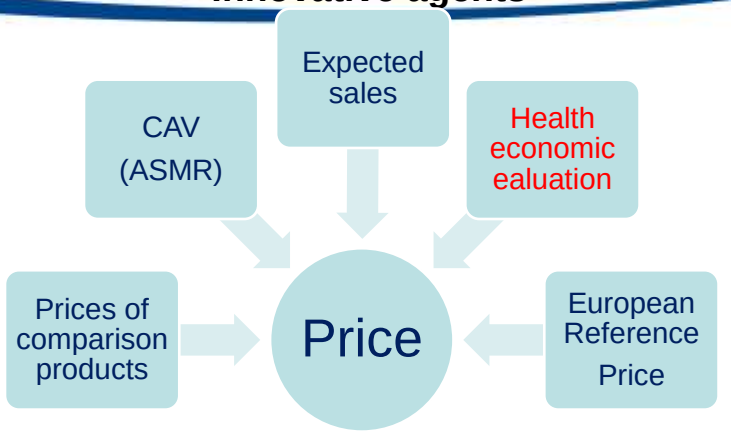
  - "Significant impact" on health expenditures (expected annual sales ≥ € 20 million) OR on healthcare organization OR on disease management

What use of EE in France in the frame of rapid HTA?



HAS

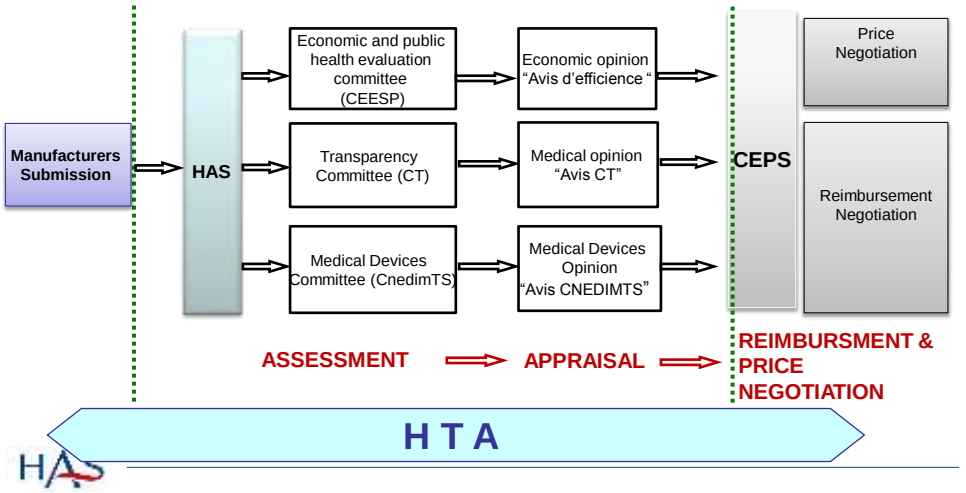
French medecines pricing system Innovative agents



HAS

HTA process in France

To provide the health care products pricing committee (CEPS) with an appraisal of the added clinical benefit and with an “Economic opinion”



CEESP economic opinion (1)

- **HAS Committee on economic and public health evaluation (CEESP) has to produce an ‘economic opinion’ within 90 days after the submission of the company**

- **HAS economic opinion comprises**
  - Submission background
  - Critical analysis of the EE submitted by manufacturers
  - ICER at the requested prices and at different price
  - Uncertainty assessment
  - (Critical analysis of optional budget impact analysis)
  - Conclusions

CEESP economic opinion (2)

- **2 years after the introduction of EE in France (Nov 2013-Oct 2015)**
  - 35 EE submitted by manufacturers assessed by HAS
  - Cancers (30%); infectious diseases (8%)
  - Negotiation process succeeded for 12 drugs and 1 vaccine (prices published in the Official Journal)
  - Negotiation process currently ongoing for 8 drugs

CEESP economic opinion (3)

- **No cost-effectiveness threshold in France**

- **Two scenarios**

1. The EE complies with HAS guideline reference case (20/30)

– Minor methodological limitations of the EE are reported

– Uncertainty around the model parameters and results are explored

→ Qualitative assessment of the efficiency of the technology

2. The EE does not comply with HAS guideline reference case (10/30)

– Major methodological limitations of the EE are reported

→ No conclusion on the efficiency of the technology

Ex. 1: Trastuzumab-emtansine (Kadcyla)

- **Therapeutic area**
  - Breast cancer
- **HTA**
  - ASMR II
  - ICER: 191 661€/QALY
- **Decision**
  - Reimbursement at 100%
  - Facial price (official journal)
    - 1798€ /100 mg (excl. VAT)
    - 4% lower than requested price
    - Additional confidential rebates

Ex. 2 Sofosbuvir (Sovaldi)

- **Therapeutic area**
  - Hepatitis C
- **HTA**
  - ASMR II (genotypes other than 3) and III (genotype 3)
  - Various ICERs depending on genotype and patient characteristics, ranging from 5 866 €/QALY to 75 518 €/QALY
  - <30 000 €/QALY for most patient sub-groups
  - Large size of the affected population → the issue is **affordability**
  - Prioritization of treatment to patients with greatest need
- **Decision**
  - Reimbursement at 100%
  - Facial price (official journal)
    - 13 667€/28 tablets (excl. VAT)
    - 24% lower than requested price
    - Lowest public price in Europe
  - Additional confidential rebates

Role, issues, and future perspectives related to economic evaluation (EE)

- **Strengthening the role of EE in the process of price negotiation**
- **But lack of social acceptability of EE in reimbursement decisions**
- **In the absence of a cost-effectiveness threshold, how to quantify the 'efficiency' in the CEESP economic opinion?**
- **Budget Impact Assessment**
- **Ensuring the sustainability of the health care system regulation by assessing the efficiency of health care strategies including primary prevention**

More collaboration between HTA agencies

- **To share information on current technology appraisals**
  - Exchange ideas on methodological issues (e.g. comparators, comparative effectiveness, cost-effectiveness models)
- **To enhance early dialogue between manufacturers and HTA agencies**
  - At national and European level