



HAUTE AUTORITÉ DE SANTÉ

# **Pricing & Reimbursement of drugs and HTA policies in France**

**National Authority for health  
(Haute Autorité de Santé), France**  
march 2014



# Medicinal Products in France



Committee for Medicinal Products for Human Use /  
Commission d'évaluation initiale du rapport bénéfice  
risque des produits de santé  
**benefit/risk assessment**

**European Commission / ANSM**  
**Marketing Authorization**

**Opinion**



**Haute Autorité  
de santé**

**Transparency Committee (TC):  
Health Technology Assessment**

**Decision**



**Ministre santé  
et sécurité sociale**

**Healthcare Product Economic Committee**  
**Price**

**Ministers  
Inscription  
on lists**

**National Health Insurance**  
**Level of co-payment**

Advertising Control

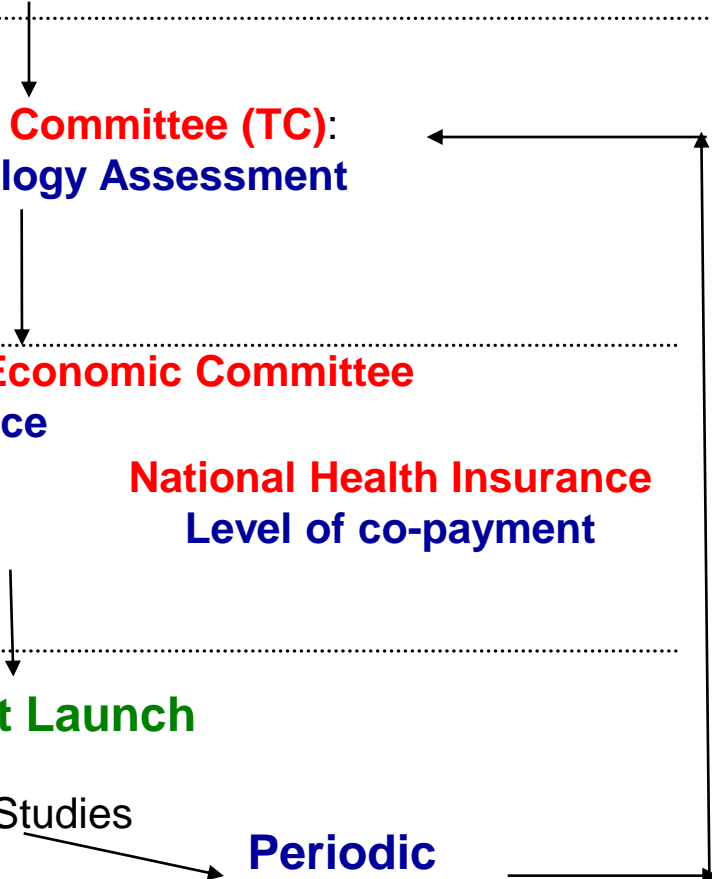
**Product Launch**

- Pharmacovigilance,
- Risk Management Plans
- Observational Studies



- Observational Studies

**Periodic  
Reassessment**



# Reimbursement and Pricing of drugs: Single Technology initial Assessment

- **All drugs have to be assessed by HAS**
  - Before inclusion on a positive list of reimbursed products
    - One list for access to Hospital Pharmacies
    - One list for admission to Community Pharmacies
  - Assessment is based on medical evidence
- **Regulated prices**
  - Based on the HAS opinion
  - Economic Committee for Health Products (CEPS)
  - Price defined by convention
- **Reimbursement and price are separately determined**
  - CEPS and HAS are separate bodies

# Reimbursement and Pricing of drugs : Single technology re-assessment

- **Re-assessment to maintain inscription on the list of reimbursed drugs**
  - STA every 5 year for drugs listed for admission to community pharmacies
  - STA at any time for all drugs when significant new information is available

# Reimbursement and Pricing of drugs: Multiple Technology Assessment

- **Multiple Technology assessment of drugs with the same indication and/or within the same pharmaceutical class**
  - on specific request from health authorities
    - Efficiency of therapeutic strategy of hypertension
  - or according to HAS program
    - 3rd generation oral contraceptives

# Assessment for reimbursement and price definition

## *What is considered ?*

- Characteristics of the disease (severity, frequency...)
- Other available medicines (comparators??)
- Quantity of effect
  
- Comparison of efficacy to other available therapeutic
- From clinical trial results to real life situation
  
- Target population
  
- Impact on health care system

Health care need

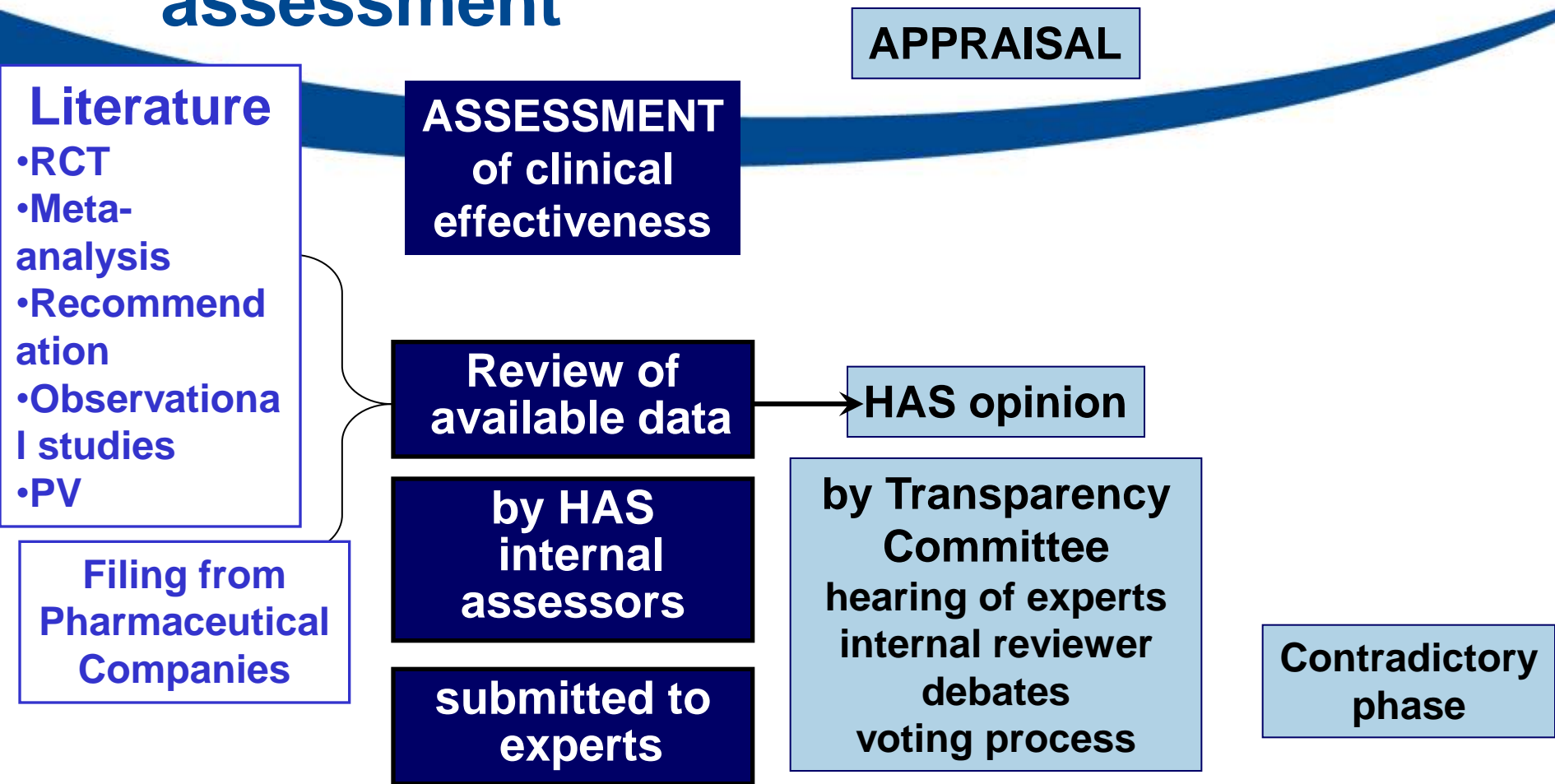
Relative efficacy

Effectiveness

# Information needed and assessed

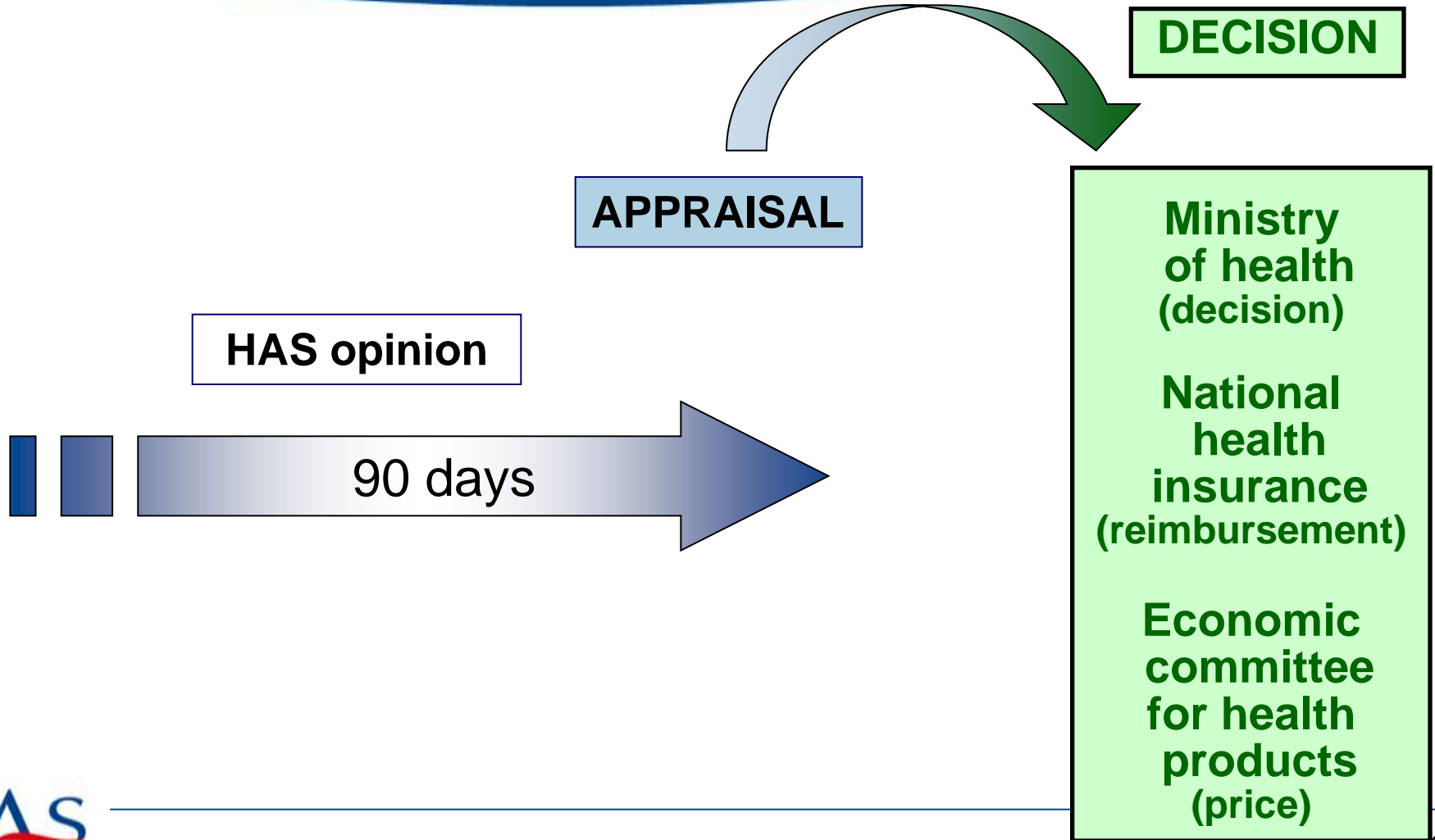
- **Efficacy**
  - Trials with correct methodology (Randomised clinical trials, meta-analysis...)
- **Tolerance**
  - Randomised clinical trials
  - Pharmacovigilance points
- **Comparators**
- **Therapeutic strategy**
  - Situate the drug within the strategy of treatment
- **Target population**
- **Interest for public health**

# HTA process for single technology assessment





# HTA process and single technology appraisal : duration



# Transparency Committee

- **Members appointed for 3 years**
  - 26 members with right to vote: specialists, GPs, pharmacists, methodologists
    - 20 members have full right to vote
    - 6 supplementary members are deputy members and can vote in case of members 'absence
    - at least 12 members are required to validate the vote.
  - 8 members are without right to vote and represent different institutions: pharmaceutical company labor party, ANSM, ministry of health (DGS, DSS), NHI (CNAMTs, RSI)
- **The Committee meets every 2 weeks**

# Content of the report

- **Administrative presentation**

- Request
- Indication

- **Assessment part**

- Health care need
- Comparators
- Efficacy data
- Tolerance data
- Therapeutic strategy

- **Opinion part**

- Actual Benefit
- Improvement in Actual Benefit
- Target population
- Recommendation
  - Inclusion on list
  - Level of reimbursement
  - Commitment : follow-up study...

# Actual benefit (Service Médical Rendu)

- **Assesses the intrinsic value of the drug**
  - Answers the question : *Should the drug be reimbursed? Does the drug clinically interesting?*
- **Takes into account 5 criteria**
  - Severity of the disease and its impact on morbidity and mortality
  - Clinical efficacy/effectiveness and safety of the medicine
  - Aim of the drug: preventive, symptomatic or curative
  - The therapeutic strategy as regards to therapeutic alternatives
  - Impact in terms of public health (burden of disease, health impact at the community level, transposability of clinical trial results)
- **The actual benefit is a recommendation for inclusion on the reimbursement list**

# When does the AB can be insufficient ?

- **Small quantity of effect, without clinical significant, with substantial adverse events,**
- **Small or very small quantity of effect, weak demonstration,**
- **Efficacy demonstrated in a population different of the MA population or uncertain transposability**
- **No place if the therapeutic, diagnostic or preventive strategy**
- **Not so severe disease, symptom and/or spontaneously curable**
- **Medicine for which exists a therapeutic alternative with demonstration of similar efficacy, more important efficacy, or less important adverse events**
- **Fixed dose combination drugs without demonstration of its interest**

# Actual benefit (Service Médical Rendu)

- The NHI defines the reimbursement rate according to the Actual Benefit level

	Reimbursement rate
<b>Important</b>	<b>65%</b>
<b>Moderate</b>	<b>30%</b>
<b>Mild</b>	<b>15%</b>
<b>Insufficient</b>	<b>not included on the positive list</b>

# Improvement in actual benefit (Amélioration du service médical rendu)

- **Assesses the relative value of the drug**
  - Answers the question : *Does the drug improve patients clinical situation, as compared to existing therapies?*
- **Measure of the clinical added value**

Major	ASMR I
Important	ASMR II
Moderate	ASMR III
Minor	ASMR IV
No clinical improvement	ASMR V

# ASMR appraisal (1)

- **Assessment of the therapeutic or diagnostic progress provided by the new drug in terms of efficacy and tolerance as compared to existing therapies**
- **Need for the appropriate identification of the pertinent comparator(s)**
- **Results of direct comparison takes into account**
  - Clinical pertinence of the main criteria
  - The evidence
  - The quantity of effect and its clinical significance
- **Indirect comparisons are acceptable if the method is realised according to recommendations**
- **Non inferiority demonstrate absence of progress: ASMR is of V**



# ASMR appraisal (2)

- **In case of demonstration of superiority the importance of the difference quantifies the ASMR**
  - A major therapeutic progress (ASMR I) is for drugs that have a demonstrated effect on mortality in a severe disease
  - Minor, moderate or important ASMR qualifies the additional clinical effect in terms of edfficacy and tolerance
  - New modalities of administration, new galenic can be considered as a progress if its clinical interest is demonstrated

# Improvement in actual benefit (Amélioration du service médical rendu)

- **Consequences**

- ASMR V: The drug can be listed only if the costs are less than the comparators
  - Lower price
  - Or induces cost saving
- ASMR I to IV: Possibility of a higher price as compared to comparators
- ASMR I to III:
  - Faster access (price notification instead of negotiation) and price consistency with European ones

# Level of drug prices according to ASMR

- **No ASMR (V)**
  - Price less than comparators
  - Or induce cost saving
- **ASMR IV**
  - If replaces a drug that will be challenged by generic drugs, no added costs for NHI
  - For other ASMR IV, depends on the target population
    - If same target population than the comparator: no price advantage (but advantage in terms of market share)
    - Situation is different if ASMR focused on a restricted population
- **ASMR I, II or III**
  - Faster access (price notification instead of negotiation) and price consistency with European ones

Consult our [Medicines advices](#)



Website: <http://www.has-sante.fr>