Health Technology Assessment, Pricing and reimbursement in France and European collaboration

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The French Healthcare system in a nutshell

• Unitary centralized state
• National Health Insurance (NHI)
  – Mandatory, coverage for the entire population
  – List of 30 ‘long term conditions’ with 100% coverage
    • 13% of French population, 60% of expenses
• Supplementary Health Insurance:
  – 90 percent of the population subscribe to supplementary health insurance
• Pharmaceuticals:
  – Positive list of reimbursed products
  – Supplementary insurance: 100% reimbursement rate for all listed drugs, no money to be paid to pharmacist in most cases
  – Regular delisting of old products
Pharma expenditure per capita (USD)

OECD Country - Year 2008 or latest available year
What is HAS?

• An independent public scientific body with financial autonomy.
• Set up in January 2005 regrouping under a single roof
  – Took over the work of previously existing institutions or Committees (ANAES, Transparency Committee, CEPP and FOPIM).
  – New missions, such as the development of a continuing professional development (CPD) scheme…
• Since 2008: explicit mission on efficiency
• Annual report presented to Parliament and the Government.
Board Members:
Prof. Gilles Bouvenot
Mr. Alain Cordier
Prof. Jean-Michel Dubernard
Dr. Cedric Grouchka
Mr. Jean-Paul Guérin
Prof. Lise Rochaix
Dr. Jean-François Thébaut

Chair of the Board
Prof. Jean-Luc Harousseau

Executive Director
Dominique Maigne

Accountability
Laure Laguerre

Work programme

Medical, Economic and Public Health assessment
Jean-Patrick Sales
Deputies: Catherine Rumeau-Pichon, Mira Pavlovic

Improvement of Quality and Safety of Healthcare
Thomas Le Ludec
Deputy: Remy Bataillon

Communication
Christiane Rossatto

General Administration and Internal Resources
Véronique Chenail
Deputy: Claude Borne

2 divisions focusing on the HAS missions

2 Supporting divisions
HAS: What for?

To improve the quality and safety of healthcare in a context of continuous medical progress

- Advice to decision-makers on reimbursement and pricing of health technologies (drugs, devices and procedures) and interventions in the field of public health
- Production of guidelines for health professionals (clinical guidelines, patient safety)
- Health care organizations accreditation and health professionals certification
- Disease management for chronic conditions
- Information to professionals, patients and the public

November 2011
Staff, Budget, Incomes

• **Staff**
  – 410 permanent staff
  – 800 surveyors (accreditation)
  – a pool of over 3 000 experts

• **2010 Budget: 68.3 million Euros**
  – Government subsidy: 8,4 M€ (12 %)
  – National Health Insurance grant: 16,8 M€ (25 %)
  – HCOs (Accreditation fees): 10,8 M€ (16 %)
  – Portion of a tax on pharmaceuticals promotion: 17,7 M€ (26 %)
  – Portion of a tax on medical devices promotion: 8,9 M€ (13 %)
  – Fees (applications for reimbursement): 4,2 M€ (6 %)
  – Miscellaneous: 1,5 M€ (2 %)

*Contributions are determined by Law (Article L.161-45 Social Security Code)*

November 2011
HAS specialist Committees

Pharmaceuticals (Transparency Committee)

Medical Devices, interventional and diagnostic procedures

Economic and Public Health Evaluation (CEESP)

- Health care for chronic conditions, disease management
- Improvement of Professional practices and Patient safety
- Accreditation of healthcare organisations
- Clinical Guidelines
Health Technology at HAS
Missions of the HTA Division

- Collaborates to assessment and appraisal of all kind of health interventions
- Provides scientific, organizational and administrative support to 3 HAS specialist committees
  - CT: Transparency Committee (Drugs) Prof. G. Bouvenot
  - CNEDiMTS: Assessment of medical devices, procedures and technologies Prof. JM Dubernard
  - CEESP: Economic and public health evaluation Prof. Lise Rochaix
Organisation of the HTA Division

• **Director of the Division: Dr Jean-Patrick Sales**
  – Deputies: Catherine Rumeau-Pichon, Dr Mira Pavlovic

• **4 departments**
  – Medicines evaluation - Anne d’Andon
  – Medical Devices evaluation - Catherine Denis
  – Diagnostic and therapeutic procedures - Sun Lee Robin
  – Economic and Public health evaluation - Catherine Rumeau-Pichon
HAS activity report for 2010

- **795** single technology appraisals (STAs) on medicines
- **159** STAs on medical devices (MDs)
  **12** reports on “homogeneous groups of MDs
- **65** HTA reports on procedures (diagnostic or therapeutic) / Technologies
- **18** « full HTA » reports including economic assessments
- **6** public health guidelines
Assessment/appraisal:

- **HAS is not a decision making body.**
  - Advice given to decision makers.

- **Two phases:**
  - assessment (internal assessors) and
  - appraisal = conclusions/judgment and advice formulation (Specialist Committees, validation by HAS board (except MDs and drugs).

- **Criteria are defined in regulatory texts that HAS must apply**
  - One criterion to conclude on the eligibility of a technology to reimbursement (takes into account some non clinical aspects (impact on public health)
  - One criterion to estimate if the technology brings some clinical progress over existing therapies
From HTA to reimbursement

Criteria:
- Actual benefit (Service rendu)
- Clinical added value (Amélioration du SR)

Appraisal Committee Guidance

CEPS
Economic Committee for Healthcare Products

Decision

Price

Drugs

MDs

Procedures

UNCAM
Nat. Health Insurance Union

Ministry of Health, M. of Social Security

Pricing negotiation

Reassessment mandatory after 2-5 years
Positive lists of reimbursed technologies. Two types of activity

- **Planned assessments**
  - Work plan adopted every year
  - Following requests from institutions, professionals, patients organisations, or on HAS initiative
  - New assessments or re-assessments (e.g. categories of drugs, devices…)
  - Full HTA

- **Rapid HTA following submission of an application dossier**
  - Drugs (Industry)
  - Devices (Industry)
  - Procedures (Professional organisations)
  - Services (ambulatory sector service providers)
Assessment of procedures

• **Types of procedures:**
  – Diagnostic tests, imaging technologies…
  – Interventional procedures (diagnostic or therapeutic).

• **Types of assessments**
  – Opinions on a single procedure
    • 45 opinions in 2010
  – Reports on complex procedures
    • 20 technological assessment reports in 2010

• **Re-assessment of common procedures**
  – indications and to promote good practices (e.g. measurement of cardiac markers) and
  – conditions under which procedures should be carried out (e.g. cataract surgery).
Assessment of medical devices

• 159 opinions for MDs issued in 2010
  – 33% reduction of average lead time for dealing with requests for inclusion on reimbursement lists (99 days).

• 12 homogeneous categories of devices reviewed

• MDs used in hospitals
  – Currently only MDs that are finances in supplement to the DRG related set price are to be assessed by HAS
  – HAS decided to extend the scope of its assessment to include MDs that are financed through DRGs
  – 2010: negative pressure treatment systems
  – Recent regulatory changes enlarged HAS remit
Coverage with evidence development for innovative MDs and procedures

- Reducing uncertainty
- Reducing risk of inappropriate decision
- Reducing risk of inappropriate use
- Additional evidence generation
- Temporary decision or periodic revision of decision
- Restricted use in a well defined frame
HTA for Public Health Measures

• **Assessments of public health measures**
  – provide the information needed to decide whether or not to implement healthcare programmes and policies.
  – specify what methods should be used, particularly in the fields of screening, prevention and the organisation of the healthcare system.

• **Some examples**
  – Advice to set up an organised national screening programme for cervical cancer (more effective than individual screening).
  – HIV screening strategies
  – Down’s syndrome screening
Drugs evaluation at HAS
Sales of reimbursable drugs - 2010

• Total sales 2010: Euros 25.5 billion.
• 1.3% increase / 2009 (3% in average for the previous 5 years)
  – community pharmacies +0.5%
  – Hospitals +6%
• Slowing down of growth due to:
  – lapsing of patents
  – growing generic substitution
  – Reduced number of new innovative drugs,
  – impact of price management
  – promotion of rational prescribing ("maîtrise médicalisée")

Source / CEPS Annual report for 2010
1. **All drugs have to be assessed by HAS**
   ✓ before inclusion on the **positive list** of reimbursed products

2. **Regulated prices.**
   ✓ Negotiating committee = CEPS (Economic Committee for Health Products) CEPS and HAS are separate entities.

3. **Link between HAS opinion and drug prices**
   ✓ Assessment of clinical added value

4. **Review every 5 year**
   ✓ or when significant new information is available.
     Assessment of added value can be revised
   ✓ Possible delistings
HTA, pricing and reimbursement:

HAS Guidance → CEPS Economic Committee for Healthcare Products → Price → Decision → NHI Union → Copayment Level

Ministry of Health, M. of Social Security
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
Question 1: Is the drug eligible for reimbursement?

Criterion 1: « AB » Actual Benefit
« SMR » Service Medical Rendu

Takes into account:
- disease (severity)
- drug: clinical effectiveness
  + impact on public health

Question 2: Does the drug bring some clinical progress over existing therapies?

Criterion 2: « Clinical added value »
« ASMR » (Amélioration du SMR)

ASMR ▶ I = major, ▶ II = important, ▶ III = moderate, ▶ IV = minor,
▶ V = no added value.
Clinical aspects
• clinical efficacy
• clinical effectiveness
• relative effectiveness

Other aspects
• disease characteristics
• target population
• impact on public health
• impact on healthcare organisation (qualitative)

Actual Benefit
- Insufficient
- Sufficient

Clinical added value
- No added value
- Added value

Results
- No reimbursement
- Reimbursement only if price inferior to comparators
- Price may be higher than comparators

HTA: HAS Guidance

Decision: Ministry
Pricing: Economic Committee
Drugs with ASMR I, II or III

% of new products* with moderate to major added value (ASMR I, II or III)

* or new indication

- 2005: 31%
- 2006: 34%
- 2007: 39%
- 2008: 13%
- 2009: 17%
- 2010: 15%
From HTA to pricing and reimbursement
CEPS Members

- Chairperson, vice-chair person
- **Ministry of Work, Employment and Health**
  - Representatives of: Director of Social Security, Director General for Health, Director of Care Provision
- **Ministry of Economy, Finance and Industry**
  - Representatives of DG for Competition, Consumer affairs and Combating fraud and DG for Competition, Industry and Services
- **NHI Bodies**
  - Representatives of CNAMTS, RSI, MSA
- **Union of complementary insurance companies**
- **Minister of Research**
Rules governing price setting

• The retail price of drugs:
  – shall be set by means of a contract between the company selling the drug and the CEPS, or by decree

• Primary considerations when setting prices:
  – additional medical benefit provided (ASMR),
  – prices of comparators,
  – forecast or recorded sales volumes,
  – foreseeable and actual circumstances surrounding use of the medicine

• Link between ASMR and price
  – drugs that provide no ‘ASMR’ as assessed by HAS and no savings on medical treatment costs’ cannot be put on the list of reimbursed products
Rules governing price setting

• **Spending objective: ONDAM**
  – Parliament adopts every year a national health spending objective (ONDAM),
  – indicative, not compulsory.

• **CEPS’ task is to obtain the most advantageous price and financial conditions for the NHI system,**

• **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.
Ongoing and expected changes
What changes?

• New laws on assessment of drugs and medical devices
  – More focus on efficiency

• Possible changes in the criteria
  – From 2 criteria (SMR- ASMR) to one single criterion?

• International and European collaboration
  – Concrete pilot actions on early dialogue
Changes in France: Towards one single integrated criterion?

• **ASMR and SMR are both, in some ways comparative**
  – SMR has to be evaluated ‘in consideration with other existing therapies’

• **Advantage of a single criterion**
  – Simpler
  – Possibility to introduce some standardised way of assessment/judgement (see AMNOG approach)
  – Better reproducibility
Changes in France: New legislative measures

Law on Social Security Financing for 2012 (LFSS 2012)
Voted 29 November 2011

• For that purpose [HTA mission], HAS produce guidance on the conditions of prescription, realization or use of health products, procedures or services as well as on their efficiency.

• In particular, HAS performs or validates the “medico-economic” studies that are deemed necessary for the purpose of Health Technology Assessment.
Health economics Committee

- A Specialist Committee of the French National Authority for Health is in charge of establishing and disseminating recommendations and health-economic guidance on the most efficient prescriptions and strategies of care.

- Naming, composition and procedural rules of this Committee are specified and decided by HAS.
Decree to complement these legislative measures

Décret d’application = decree specifying how a law should be enforced

- A decree will specify the cases in which this “medico-économic” evaluation is required, in particular for the technologies that bring added clinical benefit (ASMR), or considering the foreseen expenses or the conditions of use.

- Criteria and timeframes to be applied will be defined in the decree.
Concrete changes

• **Initial assessment, at the time of Marketing authorisation**
  – CEESP will analyse the methodological quality of the economic part of the application submitted by companies, when available.
  – This analysis will be transmitted to CEPS to better inform the price setting process

• **Full economic analysis at the time of re-assessment**
  – Together with other non clinical aspects
  – Based on additional data collection
Value-based pricing in action
The alleged advantages of the French pricing system

- The French drug pricing system has recently been presented by industry as a good ‘value based’ pricing system achieving both static and dynamic efficiency

- The price-volume contracts have been seen as effective in separating list (facial) prices from actual transaction prices in order to avoid international reference pricing

- The post launch data collection requests at listing time have been analyzed as useful in assessing real life value and to enable prices to be adjusted subsequently

=> From theory to practice
The pricing system  Role of the CEPS

• **French Pricing Committee CEPS**
  – Since 1999, the CEPS negotiates the price of each new branded drug with the drug company.
  – It is composed of representatives of sickness funds (mandatory and voluntary), ministries and industry.

• **Framework agreement** :
  – CEPS works within a 5-year framework agreement (to be renewed this year) with the industry trade union (LEEM) which makes provisions for data access, good use and expenditure growth control

• **Price/Volumes agreement** :
  – CEPS is in charge of annual individual price/volumes agreements with companies and applies sanctions in case of volume targets overshooting
The value assessment process

• HAS guidance comprises an evaluation of the clinical added value (CAV = ASMR)

• Consequence on price setting: 3 situations arise:
  – Major to moderate CAV (I, II, III): eligible for faster access at a European price (Price notification instead of negotiation)
  – No CAV (Level V): price lower than comparators (by Law)
  – Minor CAV (IV): negotiation

• Additional criteria in the CEPS pricing decision:
  – Competitors’ prices in same therapeutic indication
  – Forecast or recorded sales volumes
  – Expected and/or actual conditions of use
The French pricing system

- **Relies on two types of instruments**
  - A price definition joined with volume contracting, using clawback payments in case of overshooting (236 million paid by companies to NHI for 2009)
  - Restrictions on targeted population, based on HAS’ guidance

- **A hybrid between**
  - an international reference pricing system for technologies with major to moderate clinical added value (CAV I to III)
  - a clinical effectiveness (value) based system for minor clinical added value (CAV IV)
  - An internal reference pricing system (using price of therapeutic comparators) for no clinical added value (CAV V)
From clinical added value …

The French pricing system does rely on a partial assessment of value: the assessment of clinical added value undertaken by the transparency committee at HAS (predominantly based on individual clinical benefits)

- The therapeutic added value to society is not addressed per se at first listing
- The other price determinants (public health or industrial considerations) are balanced by the pricing committee (CEPS) but there is no decision traceability
... to collective added value

Value based pricing has to rely on the explicit and quantitative assessment of all the individual and collective value determinants.

For the French pricing system to qualify as ‘value based pricing’, additional issues must be addressed, beyond the measurement of clinical added value (relative effectiveness):

- efficiency
- organization of care
- Social values

=> HAS may increasingly contribute to this assessment
HAS progressive use of health economics

• New remit by Law in 2008
• For HTAs and for public health and good practice guidelines
• No cost-effectiveness analysis for first listing
  – Short time frame for CAV assessment
  – Price proposed by the firm not known at time of assessment
• Mostly at time of reassessment (every five years) with possible impact on CEPS price revision
  ⇒ Statines, stents, ..
• For some technologies, full HTAs (inc. ethics and social values)
  ⇒ Growth hormones for non deficient children
• Increasingly, financial impact included for first listing
Recent legal changes and implications for HAS guidance

• **6 independent official reports**
  – In 2010 – 2011, from various auditing boards (of which 3 were related to the Benfluorex scandal)

• **New Law (LFSS 2012) in order to strengthen HAS’ role in documenting the collective added value of technologies.**
  – The economic and public health assessment committee (CEESP) has been given the same legal status as the existing medical committees for drugs (transparency committee) and medical devices (CNEDIMTS)
  – Encourage companies to submit first listing applications for P&R containing medical and increasingly economic assessments. CEESP will analyse the methodological quality of the economic part of the application when available.
Foreseeable difficulties

• Due to CEPS portfolio approach to negotiation at company level, with sanctions and clawbacks on turnover in case of target overshooting => true prices differ from facial price, calling for price simulations

• Differences in prices for drugs of comparable characteristics make it difficult for NHI to convince doctors to use the most efficient course of treatment
  – Eg: Statins have been recently reviewed, and while a class effect has clearly been identified, substantial price differences remain …

• Also and more importantly: how far can the analyst go when explicitly documenting all dimensions of a price decision without trespassing the pricing authority’s role
Challenges ahead

• HAS’ experience with quantifying the individual documented and expected magnitude of the technology benefit is of high relevance when considering value based pricing ... but it only constitutes the first step

• The more recent contribution of non-medical disciplines (economics, sociology, ..) to assessing the collective added value of a technology, compared to other strategies, is also relevant and needs to be developed if the French system is to qualify as a true ‘value based system’!

• Strengthening the link between HAS guidance (based on both dimensions) and CEPS pricing policy will contribute towards a more transparent and collective assessment of value, provided economics is not perceived or used as a cost containment or rationing tool
Towards harmonisation across EU HTA bodies?

European Cooperation in HTA
HTA in its context

• “HTA’s aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value”

• Some differences between countries are linked to the context in which HTA is implemented, not to the way HTA is performed

• Example Orphan drugs situation in England, Germany and France
HTA cooperation in Europe: From 3-year projects to a permanent network

- European Network for HTA (EUnetHTA)
- 3-year projects have been run at European level, with a support from the European Commission
  - First EUnetHTA project 2006-2008
  - EUnetHTA as a Joint Action 2010-2012
  - Future EUnetHTA Joint Action 2 2012-2015

- 2011 Cross Border Healthcare Directive
  - DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 on the application of patients’ rights in cross-border healthcare
Article 15 of
Cross Border Healthcare Directive

• The Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting bodies responsible for HTA.

• Objectives of the network
  – support Member States in the provision of information on the relative efficacy as well as on the short- and long-term effectiveness when applicable, of health technologies and to enable an effective exchange of this information;
  – support the analysis of the nature and type of information that can be exchanged;
  – avoid duplication of assessments.
Measures adopted:

• shall not interfere with Member States’ competences in deciding on the implementation of HTA conclusions and
• shall not harmonise any laws or regulations of the Member States and
• shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.
HTA, pricing and reimbursement in France

- Literature
- Dossier from Pharmaceutical Company
- Review of available data
- HAS internal assessors
- HAS Transparency Committee
- Economic Committee - Ministry of Health - NHI funds
- Pricing and Decision

HAS Guidance

"ASSESSMENT"

"APPRAISAL"
International cooperation on HTA

“ASSESSMENT”

HAS internal assessors

Review of available data

“APPRAISAL”

HAS Transparency Committee

HAS Guidance

Economic Committee - Ministry of Health - NHI funds

Pricing and Decision

Literature

Dossier from Pharmaceutical Company

eunethta
What cooperation?

• **Avoid duplication of work and reduce unjustified differences in HTA reports**
  – Do all the HTA bodies have the same data in hand?
  – Is the use of existing methodologies for HTA applied in an harmonised way?

• **Improve the appropriateness of the data**
  – Initial data production (technology development)
  – Additional data generation (post launch studies)
Avoid duplication of work and reduce unjustified differences in HTA report

• Production of a common set of data to be taken into account for the local production of HTA reports:
  – « Core HTA information »

• Assessment methods: Methodological guidelines production
  - Choice of comparator
  - Clinical endpoints
  - Composite endpoints
  - Surrogate endpoints
  - Direct and indirect comparisons
  - HRQoL
  - Safety
  - Internal validity
  - Applicability
Early Dialogue between HTA bodies and companies

• Early pilots have started!
  – With voluntary participation of EUnetHTA partners (Germany, UK, Austria, Italy, Netherlands, France)
  – Coordinated by HAS (Mira Pavlovic, Anne Gourvil)
  – With support from European Commission (DG SANCO)

• Practical aspects:
  – Letter of intent: Eligibility?
  – Briefing book: Summary of available data, description of draft development plan, list of questions…
  – Meeting between sponsor and HTA bodies
Appropriateness of data produced

Disease specific guidelines

- Currently: ongoing pilot project on Alzheimer Disease Green Park Collaborative (CMTP – HTAi)
- Disease specific guidelines part of the EUenetHTA Joint Action 2 (Work Package7)
Appropriateness of data produced

Additional data collection: EUnetHTA objectives

- Definition of **criteria** to select new technologies in need of further evidence
- **database** (EVIDENT) to share information & facilitate collaboration on additional evidence generation
- Joint Action 2: For some technologies, cooperation of several HTA bodies to define a common research question and a « **common core protocol** »
- EMA – EUnetHTA cooperation
Conclusion

• Value appraisal not in the mandate of the European network (current joint action, future permanent network) of HTA bodies in Europe

• Significant actions are however performed to reduce unjustified differences between local HTA reports/guidance

• Early Dialogue is a unique opportunity for industry to appreciate the common and specific views of HTA bodies with regard to clinical and economic data to be produced during development