Introduction of Health Economics at the Haute Autorité de Santé (HAS) in France

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Agenda

- Health Technology Assessment: a shared concept with variable implementation
  - Definition
  - HTA in France: the Haute Autorité de Santé (HAS)

- Value assessment and economic decision making for pharmaceuticals and medical devices in France:
  - Medical value at the cornerstone
  - Price fixing framework: principles and limitations

- The introduction of Health Economics at the HAS
  - Why and how
  - Multiple Technology Assessment and Single Technology assessment
  - Conclusions and questions
“Health technology is the application of scientific knowledge in health care and prevention.

Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value”

(source : EUnetHTA)

- The four dimensions (medical, social, economic and ethical) are not always in the full scope of assessment, but based on an increasingly shared corpus of methodologies
- HTA agencies missions depend upon the role of HTA in the decision making processes for:
  - Reimbursement of medical goods or medical practices by health insurances or national health services
  - Guidance of practices for health professionals, based on scientific evidence and eventually efficiency
- Appraisals are based on the societal & political values prevailing in the decision process

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The Haute Autorité de santé (HAS)

- Created in 2005 by law
- National public independent body, with financial autonomy (64 millions € annual budget, 410 employees, 3,000 external experts)
- Board of directors: 8 opinion leaders with expertise in the health care sector, 6 years mandate
- Chairman designated by the Prime Minister, upon a proposition of the Minister in charge of Health
- Mission: to increase quality of health care by improving its safety, effectiveness and accessibility
  - To support health care professionals to improve their clinical practices in hospitals and community care
  - To assist public decision makers in defining the scope of health goods and services to be reimbursed by the Health Insurance
  - To promote appropriate use of care by informing patients and controlling quality of medical information

Explicit mission in Health Economics only introduced in 2008, and reinforced for pharmaceuticals and medical devices in 2011
The decision process in France: two distinct steps

**Step 1**

- Manufacturer
  - Applies for reimbursement

- Manufacturer’s price
  - Price claim

- Technical assessment
  - The Transparency committee *(pharmaceuticals)*
  - The CNEDIMTS *(medical devices & procedures)*
  - (Haute Autorité de Santé)
  - Opinions are published

- 3 months to 6 months

**Step 2**

- Reimbursement rate
  - Mandatory Health Insurance Union *(UNCAM)*

- Price fixing
  - Economic Committee for Health Care products *(CEPS)*

- Manufacturer Negotiation

- Publication in the Official Journal

- MARKET ACCESS

- 2 months

- Manufacturer
  - Applies for reimbursement of new indications, substantial changes in SCP or use, reassessment every 5 years

- 3 months to 3 years ....

- 3 months to 6 months
STEP 1: ACCESS TO REIMBURSEMENT based on SMR and ASMR

SMR (service médical rendu) or absolute medical benefit

Should the product (or the device) be reimbursed?

SMR determines the reimbursement rate for pharmaceuticals applied to public price:
- Important / Major (65% - 100%)
- Moderate (30%)
- Low (15%)
- Insufficient (no reimbursement)

Reimbursement rate for medical devices is fixed (70% of the fixed tariff)

ASMR (amélioration du service médical rendu) or additional medical benefit

Should a premium price versus existing therapies be granted?

- ASMR I – major therapeutic advance
- ASMR II – important improvement in terms of efficacy and/or safety
- ASMR III – modest progress in terms of efficacy and/or safety
- ASMR IV – minor progress in terms of efficacy and/or usefulness
- ASMR V – no therapeutic progress

A similar scale is applied to medical devices.
● What is the burden of the disease? :
  • Prevalence, incidence, prognosis
  • Available therapies and extent of unmet needs

● Is the outcome measure relevant to assess value?
  • Eg cancer therapy: tumor regression or progression free survival or overall survival? Or tolerance? Or QoL?
  • how to balance risk/benefit?

● What is the comparator?
  • Most prescribed, most recently listed, cheapest ➔ in practice extended occasionally for pharmaceuticals to off-label use or non pharmacological treatments.

● What is the evidence available?
  • Gold standard: head to head comparative trials ➔ influenced by the approval requirements
  • Numerous limitations in practice ➔ indirect comparison is second best
STEP 1 medical benefit assessment: key questions addressed by the Transparency Committee (pharma)

● Magnitude of effect? Extent of additional benefit?
  • Eg 2 weeks survival versus months or years in cancer therapy?
● What is the position in the overall therapeutical strategy?
  • First line, second line …. Or possible restriction to sub-group of patients
● What is the target population, given the position in the therapeutical strategy?
  • Qualitative and quantitative assessment of patients based on available epidemiological data
● What is the expected impact on public health?
  • Morbidity and mortality impact on the population
  • Impact on health care resources utilization and the organisation of health care provision
● How far are CTs results transferable to real life setting? What is the further evidence required?
  • Requirements for additional clinical trials, registries, observational surveys for post launch assessment

A similar approach is adopted for medical devices with consideration of required skills and equipment when necessary
The system is not discriminative enough for access to reimbursement (most drugs are rated with « important » SMR).

The system is not recognizing additional value if not well established at first reimbursement application.

Cost/effectiveness profile is not considered in the value assessment.
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**Step 1**

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    - The CNEDIMTS (medical devices & procedures)
    - (Haute Autorité de Santé)
    - Opinions are published
  - 3 months to 6 months

**Step 2**

- **Reimbursement rate**
  - Mandatory Health Insurance Union (UNCAM)
  - Price fixing
  - Economic Committee for Health Care products (CEPS)
  - Manufacturer Negotiation
  - Publication in the Official Journal
  - Market access
  - Manufacturer Applies for reimbursement of new indications, substantial changes in SCP or use, reassessment every 5 years
  - 3 months to 6 months
  - 3 months to 3 years
  - 2 months
STEP 2 : from medical value to pricing and reimbursement rate decision

- **Economic Committee (CEPS): regulators & payers**
  - 4 representatives of ministries qualified departments: Finance (budget and industry), Social Security, Hospital (DHOS) and Public health (DGS)
  - 3 representatives of the mandatory health insurances: the UNOCAM
  - 1 representative of the complementary health insurance: the UNOC

  ➔ The Decision maker unless the Ministry opposes

- **Objectives:**
  - Provide access to the best treatments for French patients, respecting equal access and equity
  - Reach better price and economic conditions for the Health Insurance Funds
  - Keep the overall reimbursable expenditure into the pre-determined budget for pharmaceuticals
Decision by the CEPS, based on the Transparency committee opinion (pharmaceuticals):

- SMR $\Rightarrow$ reimbursement rate – and value perception!
- ASMR $\Rightarrow$ reference for pricing conditions:
  - ASMR I to IV: open negotiation between companies and the CEPS
    - ASMR I, II and III: fast track procedure & international reference pricing (UK, Germany, Italy, Spain)
    - ASMR IV: price cannot produce extra cost for the Health Insurance but negotiation still open
  - ASMR V: lower price than available treatments
STEP 2 : from medical value to pricing and reimbursement rate decision

- An agreement between CEPS and the company for 3 years
  - Ex-manufacturer price agreed ➞ public price is published
  - Sales forecasts for 3 years ➞ paybacks in case of excess, or planned price cuts
  - Prices can be adjusted to dosage, duration of treatment, in relation with the price of the comparator, changes in international pricing references
  - Commitments to provide with further evidence from clinical trials, registries, observational studies
  - Risk-sharing agreements based on performance: exceptional so far

Although not a regulatory requirement, cost/effectiveness analysis and budget impact analysis submitted by companies have been occasionally taken into consideration by the CEPS for decision making in the past 10 years for pharmaceuticals; more frequently for medical devices

The methodological guidelines were initially edicted by the College of Health Economists, and a semi-formal working group at the HAS in charge of assessing quality of studies
The pricing decisions have been severely criticized by the National Court for Auditing public accounts (rapport Cour des Comptes 2011)
- the absence of transparency of the economic agreements
- absence of cost-effectiveness considerations unlike in numerous other EU countries;

The French approach allows in practice to reward innovation

However price determination is not explicitly related to
- economic benefits provided to payers or society
- arbitration for allocating resources across different diseases/ conditions

Introduction of health economics in the legal decision process
The introduction of Health Economics in the mission of the HAS is recent

● **Why was it introduced?**
  - The principle of limiting the statutory health insurance budget has been in place since 1996 and is effectively implemented since 2009.…
  - The need to reduce public budget is a constraint imposed by the European Union
    ➔ An increased conviction amongst public bodies that allocating limited resources needs to be explicitly optimized

● **What is the role of HAS in economic evaluation?**
  - To integrate the economic dimension into the definition of best medical practices
  - To assist decision makers in assessing the eventual disproportion between the cost for the community and the marginal benefit of a new medical procedure, a new pharmaceutical or a new device
The introduction of Health Economics in the mission of the HAS is recent

- How is it implemented?
  - A dedicated committee for Economic and Public Health Assessment (CEESP), chaired by Prof Lise Rochaix was set up in 2008;
  - Already about 20 studies performed;
  - A guide « methodology options for conducting economic analysis at the HAS » has been drafted and finalized by the CEESP, after consulting all stakeholders (published November 2011)
    - Mostly in line with international guidelines BUT
    - A set of recommendations reflecting the choices: e.g.
      - Cost/utility should be preferred if QoL is significantly impaired/improved & utility measured in general population
      - The societal perspective to be preferred and costs assessed irrespectively of their funders, but aggregated results have to be presented also disaggregated
      - Both costs and outcomes have to be discounted (4% up to 30 years, 2% after)
      - Non using modelling has to be justified …. 
The introduction of Health Economics in the mission of the HAS is recent

- For which decisions an economic assessment by the CEESP is required?
  - Multiple Technology Assessment (2008)
    - Upon request of the Health Insurance, the Health Ministry, the CEPS or HAS own initiative
    - To include economic dimension in designing the recommended strategy for healthcare professionals: e.g., Statins
      ➜ To encourage efficient prescribing and set up « opposable» references for positive and negative incentives for practitioners
  - Single Technology Assessment: for first application to reimbursement for pharmaceuticals (2012)
    - Upon request of the CEPS, the Transparency committee or its own initiatives
    - On a selection of pharmaceuticals, medical devices or procedures with
      - A claim by providers to be highly innovative (ASMR I to III or IV)
      - A potentially (or effective) important budget impact
      - Further indications or utilizations expected ….
      ➜ To improve transparency and rational of price fixing across different conditions
The introduction of Health Economics at HAS: conclusion or questions?

Many questions are still pending:

● How to combine the assessment by the Transparency Committee and the CEESP in the decision process?
● The role of CEPS as a potential arbitration body?
● The criteria for requiring economic assessment in reimbursement submission by the companies?
● The definition of « assessment rules » such as thresholds (Cost/life of year gained, cost/Qaly) ? Explicit (eg UK) or implicit (eg Sweden)?
● The understanding of the technicalities by decision makers …
● The overall impact on pricing decisions for pharmaceuticals in France and in the international reference pricing used by other countries?
● The transparency of assessment of assessments ….

Publication of a decree still expected …. But practice and maturation are necessary in such a new paradigm to draw conclusions on effective impact.
THANK YOU!

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