ESSEC CHAIR HEALTH ECONOMICS

HTA based on comparative clinical effectiveness

The French « exception »: life without cost-effectiveness

Introduction

- France is one of the major European markets to still resist to Nice-mania and to reject the use of formal cost-effectiveness analysis to decide on access to reimbursement;
- Why is it so?
- What else is done?
- Future trends
- Focussing for simplicity's sake on drugs

Context

- A brief reminder:
  - A universal coverage of health care expenditures, with copayments;
  - Funded by a mix of general tax (CSG) and wage taxes;
- Access to reimbursement is a ministerial prerogative….
- With a delegation for scientifc advice to the Haute Autorité de Santé

Founding principles

- The founding principles of the admission to the reimbursed basket of goods and services are the following (in their formulation for drugs):
  - all drugs (treatments) with a favourable benefit/risk ratio, as assessed by the HAS, should be accessible to patients through reimbursement, independent of their price.
  - medicines should not be reimbursed if they *"will potentially induce unjustified expenditures for the Sickness Fund, either because their public health interest is low because their efficacy is not well proven, or because they bring a minor contribution in existing therapeutic strategies, or because of the absence of severity of the diseases they address".*

Cost-effectiveness

- **Cost-effectiveness is by definition excluded as a criterion for reimbursement:**
  - The Service Médical Rendu (SMR) is the key criterion
  - It is assessed independantly of all considerations of the cost of treatment ….
- Not an utilitarian perspective, but more of an « equal opportunity for innovation » principle.

The HAS structure

- The HAS covers the activities of seven commissions, 4 of which deal specifically with admission to reimbursement:
  - The Transparency Commission, for drugs
  - The Commission for medical devices and medical procedures
  - The Recently formed Commission for Economics and Public Health

Reimbursement

- The Transparency Commission is the main actor;
- It will attribute two scores to an innovative drug:
  - The SMR: the Medical Value (Service Médical Rendu):
    - An appraisal of the benefit/risk ratio of an innovation + other considerations
  - The ASMR: The Improvement of Medical Value (Amélioration du Service Médical Rendu)
    - An appraisal of the relative value of the innovation compared to existing therapies (relative effcicay)

The SMR (1)

1. Assessment of the benefit/risk ratio of a new product:
   - Based on the EPAR
   - But which can lead to more restrictive indications than the EPAR:
     - Different perception of risk
     - Different perception of the quality of evidence
     - Identification of sub-groups for which the benefit/risk is presumed higher

The SMR (2)

2. The « public health expected impact » is supposed to reflect the collective versus the individual benefits of a new product;

   - A composite assessment combining:

      - the severity of the disease
      - the prevalence of the disease
      - the perception of an unmet need
      - the potential positive impact on the organisation of health care services

The SMR

SMR Levels

Major Value

Important Value

Moderate Value

Low value

Insufficient value

Not documented.

Comments

- Most drugs will get an « important SMR » since this leads to a 65% reimbursement rate, although the TC may have some reservations;
- The public health impact assessment is qualitative, weakly formalised and will in most cases have little impact on access to reimbursement per se:
  - Impact on the level of reimbursement
- But sometimes can lead to a refusal of reimbursement (extreme examples, Viagra)

The ASMR: Principles

- The ASMR assessment is a result of a systematic comparison of new treatments to existing ones, in terms of the magnitude of the benefit brought by innovations.
- Based on clinical data provided by the companies
- Based on indirect comparisons provied either by companies or through literature reviews provided by the staff of the HAS
- But not based on costs, since at the time of assessment, the price on the French market is not yet set…

The ASMR

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

The advice of the Commission

- Access to reimbursement:
  - Yes/No and proposed level of copayment
- Assessment of relative efficacy
- Recommendations as to reimbursed indications
- Size of potential target population, considering the recommendations.

The pricing scheme

- A pluri-annual agreement between the French State and the industry.
- To simplify:
  - ASMR 1,2,3: European prices are accepted (UK, Germany, Italy, Spain as references)
  - ASMR 4: price discussion
  - ASMR 5: no improvement expected, so average price of existing therapies (or even less)

The role of CEA

- In such a scheme, the NICE model has no room:
  - No threshold, any drugs that « works » is reimbursed
  - No across the board comparison required
- Pricing is simplified:
  - In case of a substantial retative value (1,2,3), prices are set by companies (but price/volume agreements)
  - In case of modest benefits, there is no reason for a premium price, and no need to do health economics to decide on a price!

No future for health economics?

Pressure growing….

- Public health proponents want priority setting in the allocation of resources:
  - Priorize interventions for severe and/or prevalent conditions with a strong impact on morbi-mortality (hard endpoints)
- The National Accounts Court (Cours des Comptes) insisting on economic considerations
- The Sickness Fund wants to legitimate prescription guidelines to reduce drug prescription and use (France is the first European spender on drugs per capita):
  - The Fund is eventually promoting cheaper but less effective strategies
- French health economists want to join the international community! (but no true consensus on the theoretical validity of extra-welfarism to warrant optimal resource allocation)

A new mandate for the HAS

- Since 2007 the HAS is mandated to consider economics in its advices for reimbursement decisions;
- This mandate has not been greeted fullheartedly by an agency dominated by clinicians;
- For the moment, an acceptable compromise has been found….

The Economic and Public Health Commission

- Installed in Dec 2007;
- Composed of health economists, epidemiologists, sociologists and ethicians;
- Three main mandates:
  - Recommendations on the design of cost-effectiveness analysis in post-launch studies
  - Inclusion of cost-effectiveness criterion when revising the SMR and the ASMR every five years
  - Full HTA analysis

Conclusion

- A decision making process relying mainly on clinical effectiveness and local optimization…
- Based also on a multi-dimensional approach to decision making…
- To maintain high accessibility to innovations through local optimization and ad hoc pricing policies.
- Cost-effectiveness analysis used ex post and by thearpeutic areas to encourage optimal use of resources