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

Decision

Ministre santé et sécurité sociale

Transparency Committee (TC):
Health Technology Assessment

Healthcare Product Economic Committee
Price

Ministers
Inscription on lists

National Health Insurance
Level of co-payment

Advertising Control

- Pharmacovigilance,
- Risk Management Plans,
- Observational Studies

Product Launch

- Observational Studies

Periodic Reassessment

Periodic Reassessment

- Observational Studies
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
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

Literature
- RCT
- Meta-analysis
- Recommendation
- Observational studies
- PV

Filing from Pharmaceutical Companies

ASSESSMENT of clinical effectiveness

Review of available data by HAS internal assessors submitted to experts

HAS opinion by Transparency Committee hearing of experts internal reviewer debates voting process

Contradictory phase
HTA process and single technology appraisal: duration

- HAS opinion
- 90 days
- APPRAISAL
- Ministry of health (decision)
- National health insurance (reimbursement)
- Economic committee for health products (price)
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
The NHI defines the reimbursement rate according to the Actual Benefit level

<table>
<thead>
<tr>
<th>Benefit Level</th>
<th>Reimbursement Rate</th>
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<tbody>
<tr>
<td>Important</td>
<td>65%</td>
</tr>
<tr>
<td>Moderate</td>
<td>30%</td>
</tr>
<tr>
<td>Mild</td>
<td>15%</td>
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<tr>
<td>Insufficient</td>
<td>not included on the positive list</td>
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</table>
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**
  
<table>
<thead>
<tr>
<th>Level</th>
<th>ASMR</th>
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<tbody>
<tr>
<td>Major</td>
<td>I</td>
</tr>
<tr>
<td>Important</td>
<td>II</td>
</tr>
<tr>
<td>Moderate</td>
<td>III</td>
</tr>
<tr>
<td>Minor</td>
<td>IV</td>
</tr>
<tr>
<td>No clinical improvement</td>
<td>V</td>
</tr>
</tbody>
</table>
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 if 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 efficacy 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