Health Technology Assessment and pricing in France
Current situation and evolution

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HTA in France: Current situation
HAS = Single HTA institution in France, with other missions

HAS’ mission:
To improve the quality and safety of healthcare

- **HTA**: 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
HAS, independent public scientific body set up in 2005

Pharmaceuticals (Transparency Committee)

Medical Devices, interventional and diagnostic procedures

Economic and Public Health Evaluation (CEESP)

Health care for chronic conditions, disease management

Medical information quality and dissemination

Accreditation of healthcare organisations

Clinical Guidelines

Improvement of Professional practices and Patient safety
The two main different systems in Europe

- Determination of added clinical benefit
- Price negotiation and decision

- Health economics analysis (price proposed by company)
- Decision based on the Cost/QALY estimate compared to threshold
HTA, Reimbursement and Pricing for a new drug: The main actors

HTA guidance

CEPS
Economic Committee for Healthcare Products

Price
Decision

HAS

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RÉPUBLIQUE FRANÇAISE

HAS

HAS

HAS
**Clinical aspects**
- clinical efficacy
- clinical effectiveness
- relative effectiveness

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

**Dimensions**

**Criteria**
- Actual Benefit
  - SMR
- Clinical added value
  - ASMR

**Results**
- Insufficient
- Sufficient
- No CAV(V)
- Minor CAV (IV)
- High to moderate CAV(I,II,III)

**Decision:** Ministry
**Pricing:** Economic Committee

**HTA: HAS Guidance**

**Initial listing: From HAS guidance to CEPS pricing**

- No reimbursement
- Reimbursement only if price inferior to comparators
- Price may be higher than comparators
  - ‘European’ Price

**Dimensions**

- Criteria
- Results

**Criteria**
- SMR
- ASMR

**Results**
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**Decision:** Ministry
**Pricing:** Economic Committee
### ACTUAL BENEFIT (SMR): reimbursement and copayment level

<table>
<thead>
<tr>
<th>SMR</th>
<th>Level of reimbursement by NHI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Important</td>
<td>65%</td>
</tr>
<tr>
<td>moderate</td>
<td>35%</td>
</tr>
<tr>
<td>minimal</td>
<td>15%</td>
</tr>
<tr>
<td>insufficient</td>
<td>NO REIMBURSEMENT</td>
</tr>
</tbody>
</table>
From ASMR to price setting

- **The retail price of drugs:**
  - set by contract between the company selling the drug and the CEPS, or by decree

- **Primary considerations when setting prices:**
  - Added clinical benefit ASMR as assessed by HAS
  - Price of the drug in other European countries
  - Price of comparators in France,
  - forecast or recorded sales volumes,

- **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
Link between guidance and decision

HAS Guidance

- Added clinical benefit (ASMR)
- Target population
- Request for additional study

Price

Price – Volume agreements

Risk sharing agreements
The French pricing system does rely on an assessment of value: the assessment of therapeutic added value undertaken by HAS and predominantly based on individual clinical benefits

- The therapeutic added value to society (social value) is not addressed *per se* at first listing
- The other price determinants (among which, industrial considerations) are weighed by the CEPS but there is no decision traceability
- Re-evaluation (every 5 years) may change the reimbursement and pricing decision but again is mostly based on medical benefits
## PRICES OF NEW DRUGS IN EUROPE
(2008 IMS Health)

<table>
<thead>
<tr>
<th></th>
<th>France</th>
<th>Germany</th>
<th>Italy</th>
<th>Spain</th>
<th>UK</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASMR I/II</strong></td>
<td>100</td>
<td>120</td>
<td>84</td>
<td>90</td>
<td>89</td>
</tr>
<tr>
<td><strong>ASMR III</strong></td>
<td>100</td>
<td>135</td>
<td>84</td>
<td>90</td>
<td>115</td>
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<tr>
<td><strong>ASMR IV</strong></td>
<td>100</td>
<td>136</td>
<td>107</td>
<td>112</td>
<td>127</td>
</tr>
<tr>
<td><strong>ASMR V</strong></td>
<td>100</td>
<td>126</td>
<td>99</td>
<td>108</td>
<td>119</td>
</tr>
</tbody>
</table>
2008, introduction of the assessment of efficiency

• New remit by Law in 2008
• For public health and good practice guidelines
• No cost-effectiveness analysis for drugs at first listing
• Economic assessment performed at time of class re-assessment (of therapeutic class) with possible impact on CEPS price revision
  ⇒ Statins, Drug-eluting stents, Type 2 diabetes
• For some technologies, full HTAs (inc. ethics and social values)
  ⇒ Growth hormones for non deficient children
Ongoing introduction of economic evaluation
The two main different systems in Europe

Determination of added clinical benefit

Price negotiation and decision

Health economics analysis (price proposed by company)

Decision based on the Cost/QALY estimate compared to threshold
Evolution of the French system

Determination of added clinical benefit

Price negotiation and decision

Introduction of economic evaluation to support decision on price
Evolution of the French system

- Determination of added clinical benefit
- Proposal for new criterion to replace SMR and ASMR
- Introduction of economic evaluation to support decision on price
- Price negotiation and decision
General economic context (as in other European countries)

- NHI budget (ONDAM) had to be cut down from 2.8% to 2.5% in 2012 while GDP growth will be near 0%
- In 2010 sales of reimbursable drugs represented 18% of NHI Budget
- Very high cost of new therapies (including targeted therapies)

Economic analysis to be developed to better inform decisions
Medico-economic HTA to start OCT 2013

New Law and Decree (Oct 2012) to strengthen HAS’ role in documenting the collective added value of technologies.

- **When?**
  - first listing or reevaluation

- **3. Which products?**
  - Requested ASMR I to III
  - Significant impact on health care expenses (health care organization, price, professional practices)

- **4. How?**
  - Based on data provided by the company
  - Expected or observed efficiency (comparison with existing drugs or technologies)
Economic analysis at first assessment and at the time of re-assessment

• **Initial assessment… time frame = 90 Days**
  – HAS will assess the methodological quality of the economic part of the application submitted by companies for pricing;
  – If appropriate, it will produce guidance on expected efficiency
  – Companies may ask for a hearing, then the analysis will be handed to the pricing committee (CEPS) to help with price setting and will be published on HAS website

• **Full economic analysis at the time of re-assessment**
  – Together with other non clinical aspects (ethical, sociological, societal)
  – Based on additional data collection
Methods

• General Guide available on HAS website
• Procedures to be detailed before October 2013
New criterion for clinical evaluation
Evolution of the French system

Determination of added clinical benefit

Price negotiation and decision

Proposal for new criterion to replace SMR and ASMR

Introduction of economic evaluation to support decision on price
Should the criteria (SMR/ASMR) be revised?

- The current system is complex with
  - one 4-level indicator for reimbursement (SMR)
  - and one 5-level indicator for pricing (ASMR)

- ASMR rating is not always reproducible and is considered not predictable
## Added clinical Benefit (ASMR) 2008 - 2012

<table>
<thead>
<tr>
<th>ASMR</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
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<tbody>
<tr>
<td>I-II</td>
<td>7</td>
<td>10</td>
<td>4</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>III</td>
<td>5</td>
<td>8</td>
<td>8</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>% I-III</td>
<td>13</td>
<td>18</td>
<td>14</td>
<td>5</td>
<td>16</td>
</tr>
<tr>
<td>IV</td>
<td>17</td>
<td>20</td>
<td>20</td>
<td>20</td>
<td>22</td>
</tr>
<tr>
<td>V</td>
<td>48</td>
<td>65</td>
<td>46</td>
<td>29</td>
<td>58</td>
</tr>
<tr>
<td>Nombre total d’avis</td>
<td>75</td>
<td>100</td>
<td>85</td>
<td>58</td>
<td>99</td>
</tr>
</tbody>
</table>
Towards a new criterion: ITR

- **Unique comparative indicator for both**
  - reimbursement decision
  - pricing

- **Clear definition of:**
  - relevant comparator
  - objectives and modalities of comparative studies

- **Methodological approach**
  - semi-quantitative
  - sequential

- **Parameters**
  - to be analyzed: efficacy, safety, practicability
  - might be considered: patients subgroups
  - not considered: severity of disease
ITR (relative therapeutic interest)
Process of the sequential evaluation

ELIGIBILITY ?
Comparator, end points
level of evidence (internal validity)

NO
ITR = - 1

YES
Non inferiority
ITR = 0

Superiority
invoked
Modulation by
tolerability and practicality (-1,0,1)

Improvement on
relevant end point
(0 to 3)

Modulation by
Tolerability and
practicality (-1,0,1)

Final ITR
-1, 0, 1

Final ITR
-1 to 3 or more