Pricing and Reimbursement of Medicinal Products in France

EUCOPE

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Principle abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ATU</td>
<td>French Compassionate Use</td>
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<tr>
<td>ITR</td>
<td>Relative Therapeutic Index System</td>
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<tr>
<td>MA</td>
<td>Marketing Authorization</td>
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<tr>
<td>ASMR</td>
<td>Improvement to Medical Services Rendered</td>
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<td>CEPS</td>
<td>Healthcare Products Pricing Committee</td>
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<td>HAS</td>
<td>High Health Authority</td>
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<tr>
<td>SMR</td>
<td>Medical Services Rendered</td>
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<tr>
<td>UNCAM</td>
<td>National Health Insurance Agency</td>
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1. – The drug market in France

2. – The agencies involved in drug pricing policy

3. – The tools used in drug pricing policy

4. – The specific situation for generic products

5. – Means of recourse against the decisions of the authorities concerning pricing
Overview of the drug market in France

- Sales of reimbursed drugs in 2011 = 25,731 billion €uros, in before tax manufacturer’s prices

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<tbody>
<tr>
<td>Growth rate</td>
<td>7.7 %</td>
<td>7.7 %</td>
<td>5.7 %</td>
<td>6.5 %</td>
<td>6.9 %</td>
<td>5.0 %</td>
<td>1.8 %</td>
<td>3.9 %</td>
<td>2.8 %</td>
<td>2.8 %</td>
<td>1.3 %</td>
<td>0.7 %</td>
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Source: GERS data – city market and company declarations for hospitals, CEPS use

- Slow market growth in 2011 (+0.3 % in before tax manufacturer’s prices, +0.7 % in volume consumed)
  → Several reasons:
    - political determination to control social security expenditures
    - massive arrival of generics on the market, bringing prices down
    - no major innovations in the market over the past four years

- In 2011, the average retail price of a package of drugs in France was 10.58 €uros
Two main distribution channels for drugs

Drug distribution channels

Pharmacies

Outpatients

Healthcare facilities

Hospitalized patients

MA « ATU »

Retrocession
Price out T2A
Free pricing
Retrocession
MIGAC

Retrocession
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Setting prices and reimbursement rates in France

- **Scientific body** composed of physicians, pharmacists, specialists in methodology and epidemiology
- **Drugs evaluated** when pharmaceutical companies wish to have them included on the list of reimbursed products
- Opinions rendered by the Commission are **published** on its internet site

- **To set prices**, the CEPS takes into account **several factors**: the ASMR, the price of other products having the same therapeutic purpose, the projected or current sales volumes and the real and expected conditions for use of the drug

- In the framework of setting drug prices, the CEPS can make **agreements with the manufacturers** or distributors involved, setting prices in relation to sales volume, possible discounts, or the proper use of the drug

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**Chart**

- **EU Commission or ANSM**
  - Marketing authorization
- **HAS and its transparency Commission**
  - Assessment of SMR and ASMR
  - Reassessment every 5 years
- **UNCAM**
  - Reimbursement rate
- **CEPS**
  - Price
- **Ministry of health**
  - Decision of reimbursement
  - Reassessment every 5 years

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**Legend**

- SMR: Scientific and Medical Research
- ASMR: Administrative Scientific and Medical Research
- UNCAM: Union of the National Councils of the Medical Chambers
- CEPS: Committee of Pricing and Reimbursement Systems
- ANSM: National Agency for Medicines and Health Products Safety
- HAS: French National Authority for Health

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**Field Fisher Waterhouse**
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Today:
2 main items in France:

- SMR
- ASMR

Tomorrow?
1 item in France:

- ITR
The SMR responds to the following question: **is the drug of sufficient interest to be covered by the national healthcare system?**

- It takes into account
  - the severity of the illness
  - the efficacy
  - the drug’s side effects
  - it’s role in the therapeutic strategy, with respect to other available treatments
  - it’s public health interest

- Based on scientific proof. To be confirmed by post-commercialization studies

- The pharmaceutical company must transmit information relating to the medical service rendered: financial penalties in the event of failure to do so (up to 5% of total turnover before tax made in France for the past financial year)

- **Five levels** of SMR, from Major (reimbursed at 100%) to insufficient (0%), through significant (65%), moderate (30%) and low (15%)
SMR decided in 2011 by the HAS transparency commission
(Figures from 2011 HAS activity report)

<table>
<thead>
<tr>
<th></th>
<th>Significant</th>
<th>Moderate</th>
<th>Low</th>
<th>Insuffisant</th>
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<tbody>
<tr>
<td><strong>Inscriptions</strong></td>
<td>191</td>
<td>19</td>
<td>10</td>
<td>16</td>
</tr>
<tr>
<td><strong>Indication extensions</strong></td>
<td>17</td>
<td>3</td>
<td>1</td>
<td>3</td>
</tr>
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ASMR

• The ASMR responds to the following question: **does the drug bring an improvement over available treatments? If yes, to what extent?**
• The ASMR is less important than the SMR in getting the drugs onto the list of reimbursed products, but it plays a role in setting the price
• Criteria taken into account:
  – Improvement: comparison of efficacy and tolerance data in relation to the treatments already available
  – Economies
• **Five levels** of ASMR, from level I (Major) to level V (no improvement), through level II (significant), III (moderate) and IV (low)
The Relative Therapeutic Index system

- **New system of reimbursement thought by the HAS**
  - It would replace SMR and ASMR Post-Mediator
  - The ITR would represent the clinical value of a new drug compared to the current standard of care regardless of its approval status

- **Five levels** of ITR, from ITR lower (no reimbursement) up to ITR major benefit (with an European price)

- **Criteria of assessment include:**
  - The clinical relevance of comparators
  - The clinical relevance of primary and secondary criteria
  - The validity of methodological studies presented for demonstration of superiority and non-inferiority (direct or indirect comparisons)
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The generics market

• In 2011 generics represent
  – Over one third of all packaged drugs sold
  – Over one fourth of the turnover before tax made by retail pharmacies

• **Principle** = presumption of sufficient SMR if the original is already listed

  They can also benefit from an accelerated process and are exempted from having to submit a file to
  the Transparency Commission, with the same reimbursement rate as the respective original

• **Exception** = no presumption in some few cases: indications are not the same between the
  generic and the original

• The price proposed by the generic’s distributor or the manufacturer is automatically
  accepted if the latter offers a lower price than that of the original

• In 1994, the required discount was 30 %, currently, a 55 % discount is required
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Recourse

- Administrative recourse against decisions from the Authorities
- Few disputed decisions – less than a dozen in 2011
- Most of the requests made to the Conseil d’Etat are rejected
- Where a decision is cancelled this is often based on errors of form and procedure

(eg. Conflict of interest between a Committee member or the Commission and a competing pharmaceutical company)
Examples of case law

- **Decision Addmedica, 13 March 2012**
  
  **Background**: commercialization of Siklos 100 mg. The pharmaceutical company requested that the price be set at 110 € per package, whereas the CEPS set it at 13.40 €, the price in the US

  **Decision**: pharmaceutical company’s appeal denied

- **Decision Pierre Fabre Medicament, 1 April 2005**
  
  **Background**: following a re-evaluation and an increased SMR for the Strucurn 500 mg. product, the pharmaceutical company requested an increase in price

  **Decision**: request denied, arguing that the SMR is not part of the criteria used to determine the price of a drug. No clinical study showed that Structum 500 mg. was as effective as Chrondrosulf which has the same therapeutic purpose with an higher ASMR, which confirmed the CEPS decision
Examples of case law

- **Decision Actelion, 10 January 2007**
  
  **Background**: request for a higher sale price
  
  **Decision**: request denied, the price was too high in comparison to the price in other European countries

- **Decision Jolly-Jatel, 1 December 2011**
  
  **Background**: request that the decision to strike off Rhinotrophyl be suspended
  
  **Decision**: request granted, other products in the same therapeutic class remained on the list of reimbursed products and the procedure followed by the Transparency Commission contained several irregularities (failure to examine certain documents, conflict of interest risk, etc.)
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