The French healthcare system and pharmaceutical market

What lessons for pharmaceutical companies?

— short version —

May 2013
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Introduction

This presentation provides an overview of how the French healthcare system works and what are the recent trends in the French pharmaceutical market

Key questions answered

Who are the key players in the French healthcare system?

How is the French healthcare system organized nationally and regionally?

What are the major categories of healthcare expenditures?

How does France stand in comparison with other countries?

What are the recent evolutions of the therapeutic classes, drugs, and pharmaceutical companies sales?
1. The French healthcare system

1.1. Key healthcare stakeholders

Actors in the French healthcare system can be split according to their role of decision makers, payers, suppliers or consumers

### Relations between main healthcare actors

**PAYERS**

- Social Health Insurance
  - **UNCAM¹**

**DECISION MAKERS**

- **Parliament**
  - Introduces bills (draft laws) in Parliament
  - Votes on laws
- **Ministry of Health**
  - Decides
  - Negotiate
  - Organizes the healthcare offer
- **ANSM²**
  - Supervises
- **CEPS³**
  - Can oppose
  - Notifies
- **HAS⁴**
  - Notifies
  - Alerts
  - Delegates
  - Contribute

**SUPPLIERS**

- **Pharma companies**
  - Can oppose
- **Healthcare professionals**
  - Negotiate
- **Hospitals**
  - Notifies
  - Consults

**CONSUMERS**

- **Patients**
  - Reimburse/Pay
- **Households**

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¹ Union Nationale des Caisses d’Assurance Maladie / des Organismes d’Assurance Maladie Complémentaires → National Union of Social Health Insurance Funds / of Complementary Health insurance
² Agence Nationale de Sécurité du Médicament et des produits de santé → French Health Agency
³ Comité Economique des Produits de santé → The Economic Committee on Healthcare Products
⁴ Haute Autorité de Santé → French National Authority for Health
1. The French healthcare system

1.1. Key healthcare stakeholders

... that are notably involved in the setting of a price and reimbursement rate after a drug has received its marketing authorization

Decision for reimbursement status and price negotiation

Marketing authorization* (MA)
After a favorable opinion of the MA commission (national level) or the EMA (European level)

Retail
- No request for reimbursement
- Evaluation of the Clinical Benefit (SMR) and the Improvement in Clinical Benefit (ASMR) by the Transparency Commission
- Unfavorable opinion
- Non-reimbursable drug
  - Free price (no negotiation)
- Favorable opinion
  - Reimbursable drug
  - Price Negotiation (or unilateral price setting) based on ASMR²

Hospital
- Application for approval for the use in hospitals
- Price declaration sent to the CEPS¹

ANSM
- Transparency commission

HAS
- Transparency commission

CEPS¹
- Price declaration sent to the CEPS¹

UNCAM³
- Reimbursement rate validated by UNCAM³ based on SMR⁴
- Registration on the Social Security list
- Registration on the hospital drug list, T2A⁵ list and retrocession list

Ministry of Health
- Application for approval for the use in hospitals
- Reimbursable drug
- Price Negotiation (or unilateral price setting) based on ASMR²

Marketing

* The marketing authorization is granted for specific therapeutic indications


¹ Comité Économique des Produits de Santé → The Economic Committee on Healthcare Products – ² Amélioration du Service Médical Rendu → Improvement in clinical benefit – ³ Union Nationale des Caisses d'Assurance Maladie → National Union of Social Healthcare Insurance Funds – ⁴ Service Médical Rendu → Clinical benefit – ⁵ Tarification à l’activité → Activity-based pricing
1. The French healthcare system

The price level accepted by the CEPS depends on the level of ASMR¹ (improvement in clinical benefit) granted by the Transparency Commission

### Price setting for reimbursable ambulatory drugs

<table>
<thead>
<tr>
<th>Level of ASMR¹ (improvement in clinical benefit)</th>
<th>Pricing principles</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASMR I to III (significant improvement)</td>
<td>Consistent pricing with prices in the four other major European markets²</td>
</tr>
<tr>
<td>ASMR IV (Minor improvement)</td>
<td>No increase in the cost of medical treatment³</td>
</tr>
<tr>
<td>ASMR V (no improvement)</td>
<td>Savings in the cost of medical treatment²</td>
</tr>
<tr>
<td></td>
<td>▪ Referent: Comparator used by the Transparency Commission during its evaluation or, in the case of a product line extension, the cheapest competitors</td>
</tr>
<tr>
<td></td>
<td>▪ Level of price reduction:</td>
</tr>
<tr>
<td></td>
<td>– Low: If it is considered that the new product will only take part of the market of other products already in the market</td>
</tr>
<tr>
<td></td>
<td>– High: If it is estimated that the new product may increase consumption</td>
</tr>
</tbody>
</table>

Specific clauses may be added to the price convention:

- **Risk sharing clause**: The company is bound to pay financial compensation by refunding any excess costs to the Health Insurance if sales exceed those forecast for the first four years following commercialisation
- **Price revision clauses**:  
  - **Volume clauses** are used where the ASMR for a drug has only changed for one of its indications; here sales volumes are monitored in order to ensure that the drug is only being used for the indications for which it has received its ASMR. If these volume clauses are not respected prices will be lowered or a rebate is due from the companies  
  - **Cost clauses for daily dosages**: these clauses are used where there is a range of dosages in the product range; the aim is to ensure the use of the most appropriate dose by controlling the average daily cost of the range of products. If the distribution of the consumption of different dosages is different from that forecast, the price is revised in order to re-establish the daily treatment cost which was forecast initially  
  - **Dosage or posology clauses**: the treatment cost is calculated initially on the base of the average dose; These clauses result in a price reduction if the average stated dose is exceeded

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¹ Amélioration du service médical rendu ² i.e. Germany, Spain, Italy and the UK; This situation is monitored over time and the proposed price is modified if it differs from that in other European countries ³ The cost may be calculated based on the pack price or based on the daily treatment cost for chronic diseases

Depending of the drug status, the prices for hospital drugs may be registered by the companies, set by the CEPS¹ or unregulated and proposed in tender proposals.

### Price regulation for hospital drugs

<table>
<thead>
<tr>
<th>Types of drug</th>
<th>Procedures</th>
<th>Pricing principles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovative drugs Innovative reimbursable outpatient drugs</td>
<td>Price registration by the pharmaceutical company¹</td>
<td>Consistent pricing with European prices</td>
</tr>
<tr>
<td>Non T2A expensive hospital drugs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ATU Drugs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reassigned drugs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reimbursable outpatient drugs with little or no innovative value</td>
<td>Price set by CEPS</td>
<td>No increase / savings in the cost of medical treatment³, based on the estimated patient volumes and the price of comparator drugs</td>
</tr>
<tr>
<td>Hospital drugs included in T2A</td>
<td>Unregulated price</td>
<td>Hospitals issued invitations to tender (subject to the laws of public markets) which were concluded within the law of supply and demand with pharmaceutical companies. Hence there were big differences in purchasing price between hospitals related to volume and the classes of drugs which were needed.</td>
</tr>
<tr>
<td>Non reimbursable outpatient drug</td>
<td></td>
<td>Pharmaceutical companies and distributors are free to set their prices, margins and rebates for non reimbursable outpatient drugs</td>
</tr>
</tbody>
</table>

ATU (Autorisation temporaire d’utilisation): Temporary authorization for use (limited target population)

T2A (Tarification à l’activité): Activity based costing

¹ Comité Economique des Produits de Santé → The Economic Committee on Healthcare Products
### 1. The French healthcare system

#### 1.1. Key healthcare stakeholders

In 2012, there were about 1.1 million healthcare professionals in France with the majority (68%) working in paramedic practices.

#### Healthcare professionals (2012)

<table>
<thead>
<tr>
<th>Medical practice</th>
<th>Total number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialists</td>
<td>114,866</td>
<td>33%</td>
</tr>
<tr>
<td>General Practitioners</td>
<td>101,896</td>
<td>29%</td>
</tr>
<tr>
<td>Pharmacists¹</td>
<td>72,811</td>
<td>20%</td>
</tr>
<tr>
<td>Dental surgeons</td>
<td>40,599</td>
<td>12%</td>
</tr>
<tr>
<td>Midwives</td>
<td>19,128</td>
<td>6%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>349,300</td>
<td>100%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Paramedic practice²</th>
<th>Total number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurses</td>
<td>567,564</td>
<td>76%</td>
</tr>
<tr>
<td>Physiotherapists</td>
<td>75,164</td>
<td>10%</td>
</tr>
<tr>
<td>ERM manipulators</td>
<td>30,201</td>
<td>4%</td>
</tr>
<tr>
<td>Opticians</td>
<td>25,010</td>
<td>3%</td>
</tr>
<tr>
<td>Speech therapists</td>
<td>19,963</td>
<td>3%</td>
</tr>
<tr>
<td>Chiropodists</td>
<td>12,085</td>
<td>2%</td>
</tr>
<tr>
<td>Psychomotor therapists</td>
<td>8,385</td>
<td>1%</td>
</tr>
<tr>
<td>Ergotherapists</td>
<td>8,079</td>
<td>1%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>751,363</td>
<td>100%</td>
</tr>
</tbody>
</table>

Source: INSEE & DREES (2012) – Smart Pharma Consulting analysis

¹ And 22,706 retail pharmacies (incl. overseas departments: 626)
² Excl. ambulance drivers
1. The French healthcare system

The medico-economic evaluation will be systematized for drugs with a radical, significant or moderate ASMR¹ and significant impact on health care spending

Decree of 2 October 2012 on health economic missions of the HAS²

- Implementation of the medico-economic evaluation relevant for the assessment of health products and technologies applying for registration or registration renewal on the reimbursement lists
- A medico-economic evaluation is required if two conditions are met:
  1. Application for recognition or confirmation of a radical, significant or moderate improvement in clinical benefit (ASMR¹)
  2. Product or technology that has or may have a significant impact on health spending, given:
     - Its impact on the organization and conditions of care, as well as professional practices
     - Its price
- The medico-economic evaluation is done at the time of filing an application for registration on the reimbursement lists or at the time of its renewal
- The evaluation is carried out by a commission in charge of economic assessment in public Health (CEESP³) within the HAS³, based on data provided by the company (when applying for registration or re-registration, companies are required to submit to the CEESP as well as to the CEPS, any available studies and health economic data, which are considered as necessary for the evaluation)
- The CEESP issues an opinion based on the comparative analysis between the various medically relevant therapeutic alternatives, the relationship between the costs and the medical benefit, as well as the quality of life of affected people
- The opinion of the CEESP is public, subject to adversarial proceedings and sent to CEPS

New process

- 4 October 2013 (i.e. one year after the publication in the Official Gazette)


Smart Pharma Consulting analysis

¹ Amélioration du Service Médical Rendu → improvement in clinical benefit  
² Haute Autorité de Santé → French national health authority  
³ Commission Évaluation Économique et Santé Publique  
⁴ Comité Économique des Produits de santé → The Economic Committee on Healthcare Products
1. The French healthcare system

1.2. Recent reforms

13 measures - based on the Couty Report - were selected by the Minister of Health to restore “the confidence of patients, professionals and regulators in Hospitals”

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The Couty Report – “46 proposals to restore confidence in Hospitals”

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### Context

- On September 2012, Marisol Touraine, the new Minister of Health nominated after the election of Socialist President François Hollande unveiled the “Confidence Pact” project for Hospitals with objective to restore “the confidence of patients, professionals and regulators”

- Edouard Couty, hospital director and honorary Counselor at the Court of State Auditors, in charge of preparing a report, presented the conclusions of his work on 4 March 2013 in a 72-page report with **46 proposals** grouped into four main sections:
  1. The return to the previous public hospital system (8)
  2. The reform of the hospital financing system (7)
  3. The social dialogue (24)
  4. The governance reform (7)

### Implementation

- Based on this report, the Minister of Health kept 13 measures:
  1. Definition of a local Public health system
  2. Reintroduction of the Public health service into the law
  3. Submission of a report on the reform of the T2A by June 2013
  4. Development of regional investment schemes in healthcare
  5. Investment of € 80 million in digital
  6. Revision of the prerogatives of Hospital Medical Commissions (CME¹)
  7. Review of the organization in hospital hubs
  8. Creation of a technical committee of users
  9. Consultation with the trade unions on the balance between local and national
  10. Strengthening of the regional joint conferences and formalization of a “human resources in health” chapter by the Regional health agencies (ARS)
  11. Recovery of the dynamics of local contracts to improve working conditions in hospitals (CLACT²)
  12. Reinforcement of the missions of “hygiene, safety and working conditions” committees (CHSCT³) and creation of a medical section
  13. Creation of a National Observatory of social dialogue

- The first measures should be implemented in June 2013, with the first decrees, the other should be integrated in the PLFSS¹ 2014 and in the Public Health law, announced in 2014

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Source: Ministry of Health (http://www.sante.gouv.fr/) - Nile - Hospimedia

¹ Commission médicale d’établissement – ² Contrats Locaux d’Amélioration des Conditions de Travail
³ Comité d’hygiène, de sécurité et des conditions de travail – ⁴ Projet de loi de financement de la Sécurité sociale → Social Insurance Funding Law

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The French healthcare system and pharmaceutical market 10 May 2013
1. The French healthcare system

Although many funding sources have been added to supplement the Social Security contributions, total revenues are insufficient to balance the accounts of health insurance.

Health insurance balance in 2011

<table>
<thead>
<tr>
<th>Revenue and expenditure in billions euros and as a percentage of total</th>
<th>Total net revenue</th>
<th>Total expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td>€ 171.8 bn</td>
<td>€ 180.3 bn</td>
<td></td>
</tr>
<tr>
<td>5% Other revenues¹ (€ 7.8 bn)</td>
<td>2% Transports (€ 3.6 bn)</td>
<td></td>
</tr>
<tr>
<td>14% Other taxes² (€ 24.3 bn)</td>
<td>3% Others (€ 6.3 bn)</td>
<td></td>
</tr>
<tr>
<td>35% CSG³ (€ 60.7 bn)</td>
<td>4% Management costs (€ 7.3 bn)</td>
<td></td>
</tr>
<tr>
<td>16% Medical goods (€ 28.0 bn)</td>
<td>7% Sick pays (€ 13.0 bn)</td>
<td></td>
</tr>
<tr>
<td>16% Primary care (€ 28.7 bn)</td>
<td>10% Long-term care⁵ (€ 17.9 bn)</td>
<td></td>
</tr>
<tr>
<td>46% Contributions⁴ (€ 79.0 bn)</td>
<td>42% Hospital (€ 75.6 bn)</td>
<td></td>
</tr>
</tbody>
</table>

Deficit (~€ 8.5 bn)

1. The French healthcare system

1.3. Healthcare expenditure

1. The French healthcare system

The French government has introduced several measures to reduce public expenditure on drugs by favoring the development of the retail generics market

Main governmental measures relative to generics

<table>
<thead>
<tr>
<th>Year</th>
<th>Measure Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>Introduction of generics substitution</td>
</tr>
<tr>
<td>2000</td>
<td>Objective of 25% INN prescriptions incentivized through an increase in consultation fees</td>
</tr>
<tr>
<td>2001</td>
<td>Adoption of EU Directive 27/2004, which accelerated the registration process for generics</td>
</tr>
<tr>
<td>2002</td>
<td>Launch of “Tiers Payant” system (not compulsory and limited to departments where generics penetration is low), that entails a delayed vs. immediate reimbursement for patients who buy branded drugs instead of generics</td>
</tr>
<tr>
<td>2003</td>
<td>Limitation of rebates granted to pharmacists (Loi Dutreil II / Chatel)</td>
</tr>
<tr>
<td>2004</td>
<td>10-year protection for clinical data of a molecule, starting at its first MA in Europe, for all forms, dosages and indications</td>
</tr>
<tr>
<td>2005</td>
<td>Introduction of the TFR (reference price), which entails a unique reimbursement fee for patients both for branded and generics, regardless of the actual price</td>
</tr>
<tr>
<td>2006</td>
<td>Price reduction for drugs included in the official generics directory</td>
</tr>
<tr>
<td>2007</td>
<td>- Increase of the national objective of average generics’ penetration</td>
</tr>
<tr>
<td>2008</td>
<td>- Introduction of individual incentives for pharmacists achieving substitution objectives on a selection of generic groups</td>
</tr>
<tr>
<td>2009</td>
<td>- Systematization of the “Tiers Payant” system</td>
</tr>
<tr>
<td>2010</td>
<td>- INN prescriptions facilitated by certified prescription assistance software</td>
</tr>
<tr>
<td>2011</td>
<td>- Exception to patent rights allowing generics manufacturers to use similar packaging to those used by brands (“Bertrand Law”)</td>
</tr>
</tbody>
</table>


*International non proprietary name*
Since 2005, France has lost its position as 3rd largest pharmaceutical market to China and has also been overtaken by Germany.

<table>
<thead>
<tr>
<th>Rank</th>
<th>2005</th>
<th>2010</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>USA</td>
<td>USA</td>
<td>USA</td>
</tr>
<tr>
<td>2</td>
<td>Japan</td>
<td>Japan</td>
<td>Japan</td>
</tr>
<tr>
<td>3</td>
<td>France</td>
<td>China</td>
<td>China</td>
</tr>
<tr>
<td>4</td>
<td>Germany</td>
<td>Germany</td>
<td>Germany</td>
</tr>
<tr>
<td>5</td>
<td>Italy</td>
<td>France</td>
<td>France</td>
</tr>
<tr>
<td>6</td>
<td>United Kingdom</td>
<td>Italy</td>
<td>Brazil</td>
</tr>
<tr>
<td>7</td>
<td>Spain</td>
<td>Brazil</td>
<td>Italy</td>
</tr>
<tr>
<td>8</td>
<td>Canada</td>
<td>Spain</td>
<td>India</td>
</tr>
<tr>
<td>9</td>
<td>China</td>
<td>Canada</td>
<td>Russia</td>
</tr>
<tr>
<td>10</td>
<td>Brazil</td>
<td>United Kingdom</td>
<td>Spain</td>
</tr>
<tr>
<td>11</td>
<td>Mexico</td>
<td>Russia</td>
<td>Canada</td>
</tr>
<tr>
<td>12</td>
<td>Australia</td>
<td>Australia</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>13</td>
<td>South Korea</td>
<td>India</td>
<td>Venezuela</td>
</tr>
<tr>
<td>14</td>
<td>Tukey</td>
<td>Mexico</td>
<td>Australia</td>
</tr>
<tr>
<td>15</td>
<td>India</td>
<td>South Korea</td>
<td>Turkey</td>
</tr>
</tbody>
</table>

Source: IMS Health Market Prognosis October 2011 - Smart Pharma Consulting analyses

¹ In constant USD
# 2. The French pharmaceutical market

## 2.2. Evolution of drug sales

Spending on drugs is mainly driven by ethical patent-protected drugs and generics sold in retail pharmacies.

### Evolution of drug sales by segment

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Market</th>
<th>Hospital sales</th>
<th>Generics</th>
<th>Off-patent branded drugs</th>
<th>Ethical patent-protected drugs</th>
<th>Retail sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>24,6</td>
<td>11,0</td>
<td>5,6</td>
<td>11,0</td>
<td></td>
<td>20.4</td>
</tr>
<tr>
<td>2008</td>
<td>25,4</td>
<td>11,1</td>
<td>5,7</td>
<td>11,1</td>
<td></td>
<td>20.8</td>
</tr>
<tr>
<td>2009</td>
<td>26,1</td>
<td>11,7</td>
<td>5,2</td>
<td>11,7</td>
<td></td>
<td>21.3</td>
</tr>
<tr>
<td>2010</td>
<td>26,5</td>
<td>11,8</td>
<td>5,1</td>
<td>11,8</td>
<td></td>
<td>21.4</td>
</tr>
<tr>
<td>2011</td>
<td>26,6</td>
<td>12,6</td>
<td>4,3</td>
<td>12,6</td>
<td></td>
<td>21.4</td>
</tr>
<tr>
<td>2012</td>
<td>26,3</td>
<td>13,6</td>
<td>2,2</td>
<td>13,6</td>
<td></td>
<td>20.9</td>
</tr>
</tbody>
</table>

### CAGR

- **Total Market**: +1.3%
- **Hospital sales**: +5.2%
- **Generics**: +1.3%
- **Off-patent branded drugs**: -17.1%
- **Ethical patent-protected drugs**: +4.4%
- **Retail sales**: +0.5%

### Source

GERS and Top Gers data

1. Constant ex-factory prices
2. Compound annual growth rate
3. Estimated rebated sales including products invoiced in addition of the hospitalization charges (Off T2A) and reassigned medicine sales. Estimates based on the average difference between Top Gers data (actual accounting data including rebates) and Gers data (valued based on tariff prices) for companies declaring their actual hospital sales to Top Gers.
2. The French pharmaceutical market

Since its genericization in May 2012, TAHOR\(^1\) (statin), commercialized by Pfizer, has moved from the 1\(^{st}\) to the 7\(^{th}\) rank of the retail market, which is now led by LUCENTIS.

### Top 10 products in value – Retail sales (2012)

<table>
<thead>
<tr>
<th>Product</th>
<th>2012 Sales (€ Million)</th>
<th>Market Share (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUCENTIS</td>
<td>371</td>
<td>1.8%</td>
</tr>
<tr>
<td>CRESTOR</td>
<td>308</td>
<td>1.5%</td>
</tr>
<tr>
<td>HUMIRA</td>
<td>304</td>
<td>1.4%</td>
</tr>
<tr>
<td>ENBREL</td>
<td>240</td>
<td>1.1%</td>
</tr>
<tr>
<td>SERETIDE DISKUS</td>
<td>217</td>
<td>1.0%</td>
</tr>
<tr>
<td>DOLIPRANE</td>
<td>212</td>
<td>1.0%</td>
</tr>
<tr>
<td>TAHOR</td>
<td>200</td>
<td>1.0%</td>
</tr>
<tr>
<td>SYMBICORT TURBUHALER</td>
<td>170</td>
<td>0.8%</td>
</tr>
<tr>
<td>GLIVEC</td>
<td>163</td>
<td>0.8%</td>
</tr>
<tr>
<td>INEGY</td>
<td>160</td>
<td>0.8%</td>
</tr>
</tbody>
</table>

11% of the retail market
Total market: € 20.9 billion

Average turnover = € 234.7 M

Source: GERS – Smart Pharma Consulting analysis

\(^1\) Best known as Lipitor

The French healthcare system and pharmaceutical market

Smart Pharma Consulting

May 2013
AVASTIN (monoclonal antibody) commercialized by Roche remains the best-selling drug on the French hospital market in 2012

<table>
<thead>
<tr>
<th>Drug</th>
<th>2012 Sales (€ Million)</th>
<th>Market Share (%)</th>
<th>2011 Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVASTIN</td>
<td>429</td>
<td>5.3%</td>
<td>1</td>
</tr>
<tr>
<td>HERCEPTIN</td>
<td>313</td>
<td>3.9%</td>
<td>2</td>
</tr>
<tr>
<td>MABTHERA</td>
<td>276</td>
<td>3.4%</td>
<td>3</td>
</tr>
<tr>
<td>REMICADE</td>
<td>267</td>
<td>3.3%</td>
<td>4</td>
</tr>
<tr>
<td>LOVENOX</td>
<td>178</td>
<td>2.2%</td>
<td>5</td>
</tr>
<tr>
<td>REVLIMID</td>
<td>166</td>
<td>2.1%</td>
<td>6</td>
</tr>
<tr>
<td>ADVATE</td>
<td>162</td>
<td>2.0%</td>
<td>8</td>
</tr>
<tr>
<td>ALIMTA</td>
<td>156</td>
<td>1.9%</td>
<td>7</td>
</tr>
<tr>
<td>CLAIRYG</td>
<td>156</td>
<td>1.9%</td>
<td>10</td>
</tr>
<tr>
<td>ERBITUX</td>
<td>120</td>
<td>1.5%</td>
<td>9</td>
</tr>
</tbody>
</table>

27.5% of the hospital market

Total market: € 8.1 billion

Average turnover = € 222.5 M

Source: GERS – Smart Pharma Consulting analysis

Rise - Drop - = No change vs. 2011 ranking

1 GERS data i.e. rebates are not included (actual hospital sales reached ~€ 5 billion)
2. The French pharmaceutical market

The growth of the generics segment, which slowed down from 2005 to 2010 and decreased in 2011, was boosted by political measures¹ in 2012

Evolution of the generics market (1999-2012)

Source: GERS – Smart Pharma Consulting analysis

¹ Increase of the national objective of average generics’ penetration; Introduction of individual incentives for pharmacists achieving substitution objectives on a selection of generic groups; Systematization of the "Tiers Payant" system, which exempts from upfront payment patients accepting the generic substitution – ² Constant ex-factory price – ³ Compound annual growth rate
Sales of biosimilars, which were launched in 2007, currently pertain to three therapeutic classes, and reached a total € 56 million on the retail in 2012.
Conclusion

What lessons for pharmaceutical companies?

- Apart from the **systematic disclosure of potential links of interest** between healthcare stakeholder and pharmaceutical companies, and **advantages granted to health professionnals** (the “French sunshine act”), **the relation between pharmaceutical companies and their environment should not be radically modified in the next coming years**

- However, **pharma companies should pay attention to**:
  - The **foresseeable hospital reform** based on the Couty Report¹, which could result in changes in the hospital organization and financing
  - The trend towards the **decentralization** of the decision making process in **healthcare policy**. This trend has been confirmed by some of the propositions from the Couty Report, that were selected by the French Health Minister
  - **Pharmacists and patients increasing decision power** in the choice of treatment, even if the role of physicians will remain predominant

- In order to contain the growth in healthcare expenditure regulators and payers (especially the gouvernement, the regional health bodies and the Social Security funds) are likely to:
  - **Raise the controls on the use of healthcare products**
  - Further **control and limit promotional activities of pharmaceutical companies**
  - Maintain or even increase **price pressure** notably following the loss of patents of high potential products
  - Increase **incentives and measures aiming to support the generics penetration**...

  …which should **shrink the pharmaceutical market in value**

- However, the **growing needs of an ageing population** offer growth potentials for pharmaceutical companies, mainly through the development of **patented ethical drugs, hospital and/or niche drugs**

- Because of French people’s high level of drug consumption, **France is expected to remain in the top 5 pharma markets in value by 2015**

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¹ “46 proposals to restore confidence in Hospitals”, report prepared under the direction of Mr Edouard Couty at the request of the Health Minister and released on 4 March 2013
EXEMPLES DE MISSIONS

1 Stratégie

- Evaluation de l’attrait des marchés (Produits innovants ville / hôpital – Vaccins – OTC – Génériques)
- Stratégie de croissance
  - Optimisation des investissements marketing/ventes
  - Développement d’un laboratoire sur le marché hospitalier
  - Évaluation d’entreprises en vue de leur acquisition
- Prolongation du cycle de vie des produits
  - Amélioration de la performance des produits matures
  - Adaptation de la stratégie de prix des produits
- Défense contre l’arrivée de nouveaux entrants
- Stratégie concurrentielle à l’hôpital
- Stratégie de partenariats laboratoires / officines

2 Management

- Animation et structuration de la réflexion stratégique des équipes produits
  - Identification des enjeux-clés
  - Challenge des choix stratégiques
- Formation aux prévisions de ventes (modélisation)
- Programme de développement des Directeurs Régionaux
  - Coaching des Délégués Médicaux
  - Mise en place de plans de développement
  - Conduite et accompagnement du changement
- Formation des réseaux de visite médicale aux techniques de ventes (STAR\(^1\))

3 Organisation

- Redéfinition de l’organisation d’unités opérationnelles (au niveau de filiales, de business units, etc.)
- Amélioration de l’efficacité des forces de ventes (processus de qualification, de ciblage, de segmentation)
- Amélioration du processus de distribution des médicaments
- Formalisation du processus de planification stratégique