Smart Pharma 2019
Half-year Collection

Concepts
Methods
Tools

Market Insights & Strategy
- Pharma Market Insight Studies
- The French Pharma Market 2018 – 2023 Prospects
- Succeeding on the French Biosimilars Market

Management
- Hospital & Institution Relationships in Regions
- Strategic KOL Engagement Planning
- Excellence in Execution
- Storytelling in Business
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“Becoming Smarter is our ambition – Delivering Smart Services our mission – Being Innovative our obsession”

Key features

- For the past 18 years, becoming Smarter has been our corporate ambition…

- … and providing our clients with Smarter services has been our corporate mission

- Smart Pharma Consulting has strived to allocate its resources and to develop its capabilities to:

  1. Generate and disseminate high quality insights regarding healthcare environment and pharmaceutical market

  2. Share knowledge and thoughts through consulting, training and teaching activities, as well as through numerous publications such as reports, books, articles, position papers

  3. Offer innovative viewpoints, concepts, methods, tools and solutions that outperform mainstream ones
Our triple expertise provides us with a unique positioning on the consulting market and enables us to create synergies to deliver our clients smarter services

Smart Pharma Consulting unique positioning

- Our **market research expertise** allows us to take a critical look at third party studies
- As we **carry out our own studies**, we ensure a direct quality control on the data we collect which is key to **develop fact-based analyses and recommendations**

- Our **research activities in pharma business and management** have led to **>100 publications** (articles, reports, books and position papers available on our website)
- Our teaching method, based on **educative challenges**, is acclaimed by executives and students since 1992

- Our **recommendations are supported by**:
  - Our **strong academic background**
  - Our experience in **pharma companies** and in several of the **best consulting firms** in the world
  - The **reliability** of the data that we collect
  - The **robustness** of our analyses to draw up solutions
  - Our innovative viewpoints, methods, tools, etc. (several of them having been published in peer-reviewed journals)
  - Our **ability to explain and convince** with clear, precise and concise messages

Smart Pharma Consulting is officially registered as a training organization by the French government since 2002

Sources: Smart Pharma Consulting

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1 www.smart-pharma.com – 2 Challenge of participants (e.g. analytical rigor, relevance of recommendations, quality of the oral presentations, etc.) – 3 ~935 executives trained since 2002 – 4 More than 1,830 students trained
The following selection of concepts / methods, tools and opinions, that are available on our website\(^1\), illustrates our “innovative power”

<table>
<thead>
<tr>
<th>Strategy &amp; Management</th>
<th>Concepts / Methods</th>
<th>Tools</th>
<th>Opinions</th>
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<tbody>
<tr>
<td>4Ws (What, Why, so What, What to do?)</td>
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<td>Development Strategy Matrix</td>
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<td>Preference-driven Strategy</td>
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<td>Customer Preference Card</td>
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<td>Segmentation</td>
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<td>KAM Expert Wheel</td>
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<td>The ELITE Program</td>
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<td>Pharma Reputation Index</td>
<td>Brand preference supersedes brand satisfaction</td>
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<td>4Ws</td>
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<td>Brand Preference Mix Index</td>
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<td>Behavioral Prescriber Segmentation (BPS)</td>
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<td>KEIs(^3) vs. KPIs(^4)</td>
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<td>Portfolio Strategic Matrix</td>
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<td>High Impact Strategic Interactions (H2I)</td>
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<td>Med reps are key to drive physician preference</td>
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<th>Medical</th>
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<td>KOL ID Card</td>
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<td>KOL Partnership Plan (K2P)</td>
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<td>Integrated Regional Strategic Plan</td>
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</tr>
</tbody>
</table>

Sources: Smart Pharma Consulting analysis

1 [www.smart-pharma.com](http://www.smart-pharma.com) – 2 Brazil, Russia, India, China – 3 Key execution indicators – 4 Key performance indicators
Smart Pharma Consulting is well-known for the quality of its market insight studies, offering well-documented insights and thoughtful analysis to make better decisions

Examples of market insight studies recently published

**Pharma Market Perspectives 2017 – 2023**

- Key Insights: Strategic Implications for Pharma Companies
- Position Paper: November 2018

**The French Generics Market (Including Biosimilars) Perspectives 2017 – 2022**

- Business Report: October 2017

**Hospital & Institutional Relationships in Regions**

- Benchmarking study carried out in France: January 2019
- Best-in-Class Series #9
- Recommendations for Pharma Companies

**Smart Pharma Consulting**

Market Insight Studies are designed and carried out to enhance the knowledge and the understanding of the market in order to make more relevant strategic, tactical end/or organizational decisions

Source: Smart Pharma Consulting
Smart Pharma Consulting carries out Market Insight Studies, at the 5 steps of the marketing thinking process, to help pharma companies improve their performance.

**Marketing thinking process**

1. **Competitive landscape**
   - Health authorities
   - Clients¹
   - Competitors

2. **Brand position**
   - Performance
   - Resources
   - Development

3. **Brand Objective**
   (Sales & Profit forecasting)

4. **Brand Strategy**
   - Segmentation
   - Positioning
   - Targeting

5. **Brand Tactics**
   - Corporate reputation
   - Product
   - Price
   - Place
   - Promotion
   - Service quality

Source: Smart Pharma Consulting

¹ Including payers, physicians, pharmacists, patients, patient advocacy groups, hospitals, distributors, etc.
Our ability to collect insights from all market stakeholders and our robust analytical skills allow us to deliver high value-added recommendations.

**Methodological approach**

### Clients
- Physicians
- Pharmacists
- Patients
- Hospitals
- Distributors
- Payers
- Learned societies
- Unions
- ...

### Health authorities
- EMA
- FDA
- ANSM
- CEPS
- HAS
- ARS
- ...

- **Marketing authorization**
- **Market access** (price and reimbursement)
- **Therapeutic guidelines**
- **Advertising and promotion regulations**

### Competitors
- Innovators
- Generic companies
- Biotech companies
- OTC companies
- ...

- **Benchmarking**
- **Differentiating factors**
- **Growth drivers / orientations**

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**Source:** Smart Pharma Consulting
Smart Pharma Consulting is used to carrying out studies to better know and understand healthcare systems through in-depth desk researches and individual interviews.

**Market studies targeted at health authorities**

### Types of studies recently undertaken

- **Organization of health systems**
  - Research on health systems across the world
  - Market access systems by country
  - Study of the organization, the composition and the strategic priorities of regional health bodies

- **Health Policies**
  - Analysis of healthcare reforms across Europe
  - Study of healthcare expenditure containment policies
  - Comparison of health policies regarding Rx-to OTC switches in Europe

- **Pricing and reimbursement**
  - Analysis of decision-making processes and key decision criteria re. pricing and reimbursement
  - Study of the copayment policies of supplementary health insurance funds re. drugs according to the reimbursed level by the Social Insurance

**Source:** Smart Pharma Consulting
Smart Pharma Consulting has interviewed hospitals and regional health authorities collaborators to evaluate the impact of a new measure on drug performance

**Example: Measure to enhance drug prescription quality and efficiency**

The French health authorities have recently introduced contracts between hospitals, regional health agencies and regional health insurance through which physicians are encouraged to prescribe more generics and biosimilars

### Objective

- Development of generics and biosimilars prescription at hospital level to enhance drugs cost containment

### Action plan

- Promotion of generics prescription in the reference list
- Promotion of biosimilars prescription in the reference list
- Increase in the share of generics and biosimilars in hospital purchases

### KPIs

- % of generics in the reference list prescribed at hospital level and delivered in retail pharmacies
  - **National target: 45.5%**
- % of hospital biosimilars prescriptions in the reference list
  - **National target: 70%**
- % of hospital generics and biosimilars purchased in units

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Smart Pharma Consulting is used to collecting and analyzing information about all pharma companies clients involved on the retail and the hospital markets.

Market studies targeted at clients

<table>
<thead>
<tr>
<th>Types of studies recently undertaken</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New launches</strong></td>
</tr>
<tr>
<td>- Impact assessment of new product launches</td>
</tr>
<tr>
<td>- Brand positioning studies and market segmentation</td>
</tr>
<tr>
<td><strong>Generics / Biosimilars</strong></td>
</tr>
<tr>
<td>- Attitudes and behavior of key stakeholders regarding generics and biosimilars</td>
</tr>
<tr>
<td><strong>Reimbursement rate changes / Rx-to-OTC switches</strong></td>
</tr>
<tr>
<td>- Impact assessment of changes in reimbursement rate or Rx-to-OTC switches on clients attitude</td>
</tr>
<tr>
<td><strong>Commercial policy</strong></td>
</tr>
<tr>
<td>- Discounts and associated services offered to pharmacists</td>
</tr>
<tr>
<td>- Analysis of pharmacists expectations regarding direct sales offers</td>
</tr>
<tr>
<td>- Price sensitivity studies</td>
</tr>
<tr>
<td><strong>Decision-making process in hospitals</strong></td>
</tr>
<tr>
<td>- Listing / purchasing in hospitals</td>
</tr>
<tr>
<td>- Conditions of introduction and deployment of new care practices in hospitals</td>
</tr>
<tr>
<td>- Physicians prescribing trends in oncology</td>
</tr>
</tbody>
</table>

Illustration

Clients (payers, physicians, pharmacists, patients, PAGs, hospitals, distributors, etc.)

Opinion

Behavior

Strategy

Management

Organization

Attitude

Source: Smart Pharma Consulting

1 Patient Advocacy Groups
Smart Pharma Consulting is able to figure out protocols and disease management in countries where there is little data published, by interviewing stakeholders.

**Example: Colorectal cancer (CRC) management in Kazakhstan**

**Patients**
- **General practitioners**
- **Oncologists**
  - Polyclinic / medical centers

**Oncology oncologists**
- Intestinal obstruction / enterostasis
  - No intestinal obstruction / enterostasis

**Final diagnosis**
- Localization, dimensions, type/form

**Initiation of treatment**
- Surgery
  - Oncologic centers / hospitals
  - 1. Chemotherapy
  - 2. Radiotherapy
  - 3. Surgery
  - 4. Adjuvant chemotherapy
    - Oncologic centers

**Follow up of treatment**
- Follow-up in an oncologic centre or in a day hospital by oncologists
  - Ambulatory:
    - 1st year: every 3 months
    - 2nd year: every 6 months
    - 3rd year: once a year

Source: Smart Pharma Consulting
Smart Pharma Consulting assesses regularly the degree of physicians preference for competing brands with the help of the “Brand Preference Mix” concept.

**Example: Assessment of brand preference in the respiratory market**

The Brand Preference Mix (BPM) helps determine the key prescribing drivers that can be activated to enhance prescribers preference for a brand, and thus increase its market share.

**General Practitioners**

"When you decide to prescribe a maintenance treatment in COPD over another one, what is the relative weight in your decision of the three following components?"

- **COMPANY A**
  - BPM Index calculation: $\left(72\% \times 7.8\right) + \left(15\% \times 6.4\right) + \left(13\% \times 6.4\right) = 7.4$

- **COMPANY B**
  - BPM Index calculation: $\left(72\% \times 7.8\right) + \left(15\% \times 7.5\right) + \left(13\% \times 7.9\right) = 7.8$

- **COMPANY C**
  - BPM Index calculation: $\left(72\% \times 7.9\right) + \left(15\% \times 7.2\right) + \left(13\% \times 7.0\right) = 7.7$

- **COMPANY D**
  - BPM Index calculation: $\left(72\% \times 8.0\right) + \left(15\% \times 6.6\right) + \left(13\% \times 7.4\right) = 7.7$

Source: Smart Pharma Consulting

1 Developed by Smart Pharma Consulting (see position paper “How to get physicians prefer your brand?” on: www.smart-pharma.com)
The in-depth knowledge and understanding of the market, through regular studies, enables Smart Pharma Consulting to produce complex and insightful analyses.

**Example: Economic structure of retail pharmacies in France**

Average annual turnover of a retail pharmacy in 2017: €1,627 K
(public price excluding VAT)

<table>
<thead>
<tr>
<th>Segment</th>
<th>% of sales</th>
<th>% of sales</th>
<th>Average profitability</th>
<th>Average sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reimbursable prescription drugs (ethicals &amp; semi-ethicals)</td>
<td>44%</td>
<td>25%</td>
<td>28%</td>
<td>€235 K</td>
</tr>
<tr>
<td>Reimbursable generics</td>
<td>28%</td>
<td></td>
<td>50%</td>
<td>€149 K</td>
</tr>
<tr>
<td>Other healthcare products (non-drugs)</td>
<td>16%</td>
<td>36%</td>
<td>34%</td>
<td>€82 K</td>
</tr>
<tr>
<td>Non-reimbursable drugs (OTC &amp; &quot;lifestyle&quot; Rx drugs)</td>
<td>12%</td>
<td>18%</td>
<td>14%</td>
<td>€61 K</td>
</tr>
<tr>
<td>Reimbursable generics</td>
<td>57%</td>
<td></td>
<td>50%</td>
<td>€928 K</td>
</tr>
</tbody>
</table>

Average commercial profitability = 32%

Relative weight of each segment within total sales (total = €1,627 K)

Source: Smart Pharma Consulting
Smart Pharma Consulting is used to carrying out patient surveys to understand patients behaviors and motivations

Example: Generics substitution refusal by patients

“Why do you refuse generics substitution?”

**DUROGESIC**
- Perception of a risk of loss of efficacy: 7
- Negative influence of the GP: 6
- Perception of a risk of side effects: 3
- Systematic refusal of generics: 1
- Habit of taking the originator: 1
- Drugs picked up by a third party: 1
- Waiting for the prior agreement of the GP: 1

**RISPERDAL**
- Perception of a risk of loss of efficacy: 11
- Negative influence of the GP: 10
- Perception of a risk of side effects: 8
- Galenic less convenient or pleasant: 5
- Risk of confusion: 4
- Past disappointment with a generic: 3
- Habit of taking the originator: 3
- Systematic refusal of generics: 1

**SUBUTEX**
- Galenic less convenient or pleasant: 20
- Perception of a risk of loss of efficacy: 12
- Negative influence of the GP: 7
- Resale/traffic more complicated: 7
- Perception of a risk of side effects: 2
- Risk of confusion: 2
- Past disappointment with a generic: 1
- Habit of taking the originator: 1

Source: Smart Pharma Consulting
Smart Pharma Consulting carries out various types of benchmarking and competitive intelligence studies in the pharmaceutical sector, following a strict code of ethics.

### Types of studies recently undertaken

- **Organizational benchmarking**
  - Surveys on organizational models
  - Surveys on different jobs in the pharmaceutical industry
  - Investigation of headcounts and the resources allocation

- **Process benchmarking**
  - Best practices identification
  - Surveys on adoption of new sales and marketing tools (CRM, trigger marketing, digital media, etc.)

- **Competitive intelligence**
  - Identification of future entrants and impact assessment
  - Investigation of product launches (dates and conditions)
  - Promotional investments assessment
  - Pricing policy at hospital

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Source: Smart Pharma Consulting
As shown in this example, Smart Pharma Consulting is able to realize organizational benchmarking such as detailed headcount surveys.

**Example:** Headcount survey in small to mid-sized pharma companies

<table>
<thead>
<tr>
<th>Competitors</th>
<th>Pharma company A</th>
<th>Pharma company B</th>
<th>Pharma company C</th>
<th>Pharma company D</th>
<th>Pharma company E</th>
<th>Pharma company F</th>
<th>Pharma company G</th>
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<td><strong>Total headquarters</strong></td>
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<td>19.0</td>
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<td>28.5</td>
<td>93.5</td>
<td>36.0</td>
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<td><strong>Sales Reps – GPs</strong></td>
<td>66</td>
<td>8</td>
<td>48</td>
<td>160</td>
<td>20</td>
<td>111</td>
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<td>0</td>
<td>10</td>
<td>0</td>
<td>6</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>First line managers – Specialists &amp; hospital</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>KAM &amp; others</td>
<td>0</td>
<td>0.5</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total field forces</strong></td>
<td>83.0</td>
<td>19.5</td>
<td>52.0</td>
<td>189.0</td>
<td>23.0</td>
<td>133.0</td>
<td>40.0</td>
<td>77</td>
</tr>
<tr>
<td><strong>Grand total</strong></td>
<td>112.5</td>
<td>50.5</td>
<td>71.0</td>
<td>209.5</td>
<td>51.5</td>
<td>226.5</td>
<td>76.0</td>
<td>114</td>
</tr>
<tr>
<td><strong>Number of therapeutic areas</strong></td>
<td>8</td>
<td>5</td>
<td>5</td>
<td>7</td>
<td>1</td>
<td>9</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td><strong>Number of products</strong></td>
<td>18</td>
<td>7</td>
<td>16</td>
<td>17</td>
<td>1</td>
<td>32</td>
<td>16</td>
<td>15</td>
</tr>
</tbody>
</table>

Source: Smart Pharma Consulting
Smart Pharma Consulting interviewed service providers and pharma companies to survey the remote e-detailing adoption, identify best practices and assess the impact

**Example: Benchmarking of remote e-detailing practices**

**Context**
- Specific needs to strengthen detailing:
  - Inform physicians about new indications and side effects of non-promoted products
  - Vacancies
  - Campaigns with temporary increase of targeted physicians
  - Geographic dispersion of physicians (Russia)
  - Limited access to physicians (Sweden, Turkey)

**Objectives**
- Increase the reach of the message by expanding the target
- Improve the efficacy of communication by increasing the call frequency
- Reduction of overall detailing costs

**Implementation**
- France: sales reps 100% dedicated to remote e-detailing, quantitative approach (20 contacts/day)
- Italy: sales reps 100% dedicated to remote e-detailing, qualitative approach (retention goal)
- Russia, Sweden: implementation of hybrid sales reps (face-to-face and remote e-detailing)

**Results**
- France: some physicians systematically refuse remote e-detailing
- Italy: 35%-40% of physicians regularly accept remote e-detailing
- Russia and Sweden: increase of call frequency

**Key learning**
- Remote e-detailing does not suit all physicians, hence, before implementing it, to identify those who:
  - Can have online access
  - Are likely to accept remote e-detailing
- The quality of calls is key to build a long term relationship with physicians, thus it is important to:
  - Train the sales force properly
  - Propose interesting and useful contents, meeting customer expectations and needs
  - Fix appointment by telephone rather than by e-mail (risk of spamming)

Source: Smart Pharma Consulting
Through desk research and interviews, Smart Pharma Consulting has been able to estimate the magnitude of generics price war overtime on the French hospital market.

**Example: Hospital generics pricing**

### Zometa case study in France

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of generics players</th>
<th>Est. price on hospital market</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>J</td>
<td>2</td>
<td>€210</td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>3</td>
<td>€110</td>
<td></td>
</tr>
<tr>
<td>M</td>
<td>4</td>
<td>€70</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>5</td>
<td>€70</td>
<td></td>
</tr>
<tr>
<td>S</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>O</td>
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<td>M</td>
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<tr>
<td>D</td>
<td></td>
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</tr>
</tbody>
</table>

**Competitors**

- Zometa (zolendronic acid), marketed by Novartis, is a bisphosphonate used in:
  - The prevention of bone complications in adult patients with advanced malignant disease with bone involvement
  - The treatment of tumor-induced hypercalcemia in adult patients
- The first generic, marketed by Sandoz, entered the market mid-May 2013, a week before Mylan. Fresenius launched its 4 mg version in June, Pfizer (ex-Hospira) in May and Medac in August
- Competition on price is usually even more aggressive in hospitals when there are more than one company marketing a generic version
- According to a generics company: “This behavior is illogical and is prejudicial for all generics companies as this price does not support the market and does not permit us to offer associated services”
Smart Pharma Consulting rigorous and evidence-based analyses allow to transform information into actionable and added-value recommendations to pharma companies.

**Methodological approach**

**Performance**
- In-depth historical sales analysis

**Development**
- Brand value assessment in a partnership perspective
- Potential partnership identification (e.g. in- and out-licensing)

**Resources**
- Sensitivity to promotion
- Sales force sizing
- Competencies requirement

**Pharma Market Insight Studies**

2. Brand Position

Source: Smart Pharma Consulting
Smart Pharma Consulting regularly carries out in-depth brands analyses to get a comprehensive understanding of the dynamics of their performance.

**Example:** Historical analysis of COPD products

**Million packs (MAT\(^1\) September)**

<table>
<thead>
<tr>
<th>Year</th>
<th>Total restated LAMA market</th>
<th>Incruse (GSK)</th>
<th>Spiriva Respimat (Boehringer)</th>
<th>Seebri Breezhaler (Novartis)</th>
<th>Spiriva (Boehringer)</th>
<th>CAGR(^2) 2013-2017</th>
<th>Evolution 2016-2017</th>
<th>Market share 2013</th>
<th>Market share 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>3.82</td>
<td>0.28</td>
<td>0.38</td>
<td>3.08</td>
<td>0.53</td>
<td>-0.5%</td>
<td>+17.6%</td>
<td>6.8%</td>
<td>0%</td>
</tr>
<tr>
<td>2014</td>
<td>4.27</td>
<td>0.33</td>
<td>0.44</td>
<td>3.08</td>
<td>0.56</td>
<td>+4.0%</td>
<td>-</td>
<td>6.8%</td>
<td>3.8%</td>
</tr>
<tr>
<td>2015</td>
<td>4.44</td>
<td>0.09</td>
<td>0.44</td>
<td>3.08</td>
<td>0.56</td>
<td>+4.1%</td>
<td>+69.6%</td>
<td>6.8%</td>
<td>13.3%</td>
</tr>
<tr>
<td>2016</td>
<td>4.10</td>
<td>0.47</td>
<td>0.52</td>
<td>2.76</td>
<td>0.15</td>
<td>-7.6%</td>
<td>-</td>
<td>6.8%</td>
<td>13.3%</td>
</tr>
<tr>
<td>2017</td>
<td>4.02</td>
<td>0.53</td>
<td>0.56</td>
<td>2.76</td>
<td>0.15</td>
<td>-2.1%</td>
<td>+8.2%</td>
<td>6.8%</td>
<td>14.1%</td>
</tr>
</tbody>
</table>

LAMA market defined here as the combination of all LAMA drugs specifically prescribed in COPD.

\(^1\) Moving Annual Total – \(^2\) Compound Annual Growth Rate

Source: Smart Pharma Consulting

Smart Pharma 2019 – Half-Year Collection

July 2019 22
Smart Pharma Consulting can help pharma companies assess the sensitivity of their brands to promotional investments in quantitative and qualitative terms.

**Example: Sensitivity to promotional investments**

**Performance & share of voice**

- **Market Share**
  - Share of voice - Specialists
  - Share of voice - GPs

**Promotional mix**

- **Investment per target in €M**
- **Other investments in €M**
- **Calls in €M**

**Target mix**
- Pharmacists
- Specialists
- GPs

**Media mix**
- Congress
- Press
- Samples
- Clinical trials

Source: Smart Pharma Consulting
Based on rigorous market analyses and an effective methodology\(^1\), Smart Pharma Consulting can help identify potential partners for in- or out-licensing deals

**Example:** Identification of partners for an out-licensing deal

---

**Filter 1**

**“Presence in dermatology”**

- **All pharma companies** 2,596
- **Excluded companies** 1,819
- **Retained companies** 777

**Inclusion criteria**

- Sales in dermatology

---

**Filter 2**

**“Major players in dermatology”**

- **Excluded companies** 771
- **Retained companies** 6

**Inclusion criteria**

- In the top 20 companies in dermatology in all EU5 countries
- Company A
- Company B
- Company C
- Company D
- Company E
- Company F

---

\(^1\) Developed by Smart Pharma Consulting (see position paper “Best-in-Class Pharma BD&L” on: www.smart-pharma.com)
Smart Pharma Consulting is regularly asked by pharma companies to build scenarios to estimate sales and profits objectives according to the forecast method.

Methodological approach

- **Projection**: Objectives based on historical trends, considering “other things being equal”
- **Ambition**: Objectives based on top management commitment to shareholders (top – down approach)
- **Forecast**: Objectives based on projections adjusted according to anticipated:
  - Market events (new regulations, new market entrants, changes in customers behaviors, etc.)
  - Company events (new marketing authorization, positive clinical study results, sales force cut, etc.)
A patient approach based on epidemiological data, diagnosis and treatment rates can be applied to estimate the evolution of a market size and of a brand market share.

### Example: Sales forecasting in the osteoporosis market

#### CAGR

<table>
<thead>
<tr>
<th>Year</th>
<th>Women aged 50 or more</th>
<th>Prevalent to osteoporosis with at least two vertebral fractures</th>
<th>Diagnosed</th>
<th>Treated with PTH drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>14,169</td>
<td>36</td>
<td>18</td>
<td>11</td>
</tr>
<tr>
<td>2028</td>
<td>15,599</td>
<td>45</td>
<td>22</td>
<td>13</td>
</tr>
</tbody>
</table>

### Prevalence

- **Prevalence** (+2.3% on average per year) increases faster than the total **population of women aged 50 or more** (+1.0% p.a.) because of a mixed effect:
  - **Ageing effect (baby boomers):** women aged 75 and more will represent ~31% of the women aged 50 and more in 2028, vs. ~27% in 2018.
  - In addition, the prevalence rate within women aged 75 and more (~0.85%) is much higher than the prevalence of women aged between 50 and 74 years (~0.04%).

### Diagnosis and treatment rates

- Diagnosis and treatment rates have been maintained at a **stable rate** over the period, in accordance with interviewed KOLs feedback:
  - **Diagnosis** rate: 50% of prevalent women
  - **Treatment** rate: 60% of diagnosed women
A market approach based on the adjustment of historical sales projections can also be applied to estimate the dynamics of a brand on its market.

**Example: Sales forecasting in the oncology market**

<table>
<thead>
<tr>
<th>Sales in '000 units</th>
<th>Total market</th>
<th>Product A</th>
<th>Product B</th>
<th>Product C</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>2,762</td>
<td>968</td>
<td>999</td>
<td>999</td>
</tr>
<tr>
<td>2019</td>
<td>2,768</td>
<td>1,057</td>
<td>1,047</td>
<td>947</td>
</tr>
<tr>
<td>2020</td>
<td>2,848</td>
<td>1,133</td>
<td>1,121</td>
<td>952</td>
</tr>
<tr>
<td>2021</td>
<td>2,897</td>
<td>1,214</td>
<td>1,295</td>
<td>944</td>
</tr>
<tr>
<td>2022</td>
<td>2,947</td>
<td>1,379</td>
<td>1,379</td>
<td>936</td>
</tr>
<tr>
<td>2023</td>
<td>2,999</td>
<td>1,462</td>
<td>1,462</td>
<td>928</td>
</tr>
<tr>
<td>2024</td>
<td>3,051</td>
<td>1,661</td>
<td>1,661</td>
<td>928</td>
</tr>
</tbody>
</table>

**CAGR**
- Total market: +1.7%
- Product A: -3.0%
- Product B: +7.1%
- Product C: -1.2%

**Market share (2018-2024)**
- Total market: 28.8% → 25.2% → 21.7%
- Product A: 35.1% → 41.9% → 47.9%
- Product B: 36.2% → 32.9% → 30.4%
Smart Pharma Consulting can develop for pharma companies models to forecast the potential margin of selected products

**Example: Profit forecasting for a CNS product**

![Diagram showing profit forecasting for a CNS product]

- **Sales**
- **EBITDA**
- **R&D**
- **G&A**
- **Marketing & Sales**
- **COGS**

**Forecasted P&L**

<table>
<thead>
<tr>
<th>Year</th>
<th>Sales</th>
<th>EBITDA</th>
<th>R&amp;D</th>
<th>G&amp;A</th>
<th>Marketing &amp; Sales</th>
<th>COGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>630</td>
<td>145</td>
<td>82</td>
<td>69</td>
<td>176</td>
<td>158</td>
</tr>
<tr>
<td>2019</td>
<td>670</td>
<td>174</td>
<td>80</td>
<td>74</td>
<td>181</td>
<td>161</td>
</tr>
<tr>
<td>2020</td>
<td>660</td>
<td>165</td>
<td>79</td>
<td>73</td>
<td>178</td>
<td>165</td>
</tr>
</tbody>
</table>

**EBITDA (% of sales)**

- 2018: 23%
- 2019: 26%
- 2020: 25%

Source: Smart Pharma Consulting

1 Constant ex-factory prices, excluding VAT
Smart Pharma Consulting proposes highly effective positioning and segmentation methods that are associated with specific data collection about customers.

### Positioning & Segmentation studies

#### Brand Preference Mix (BPM)
- **Corporate reputation**
- **Brand attributes**
- **Service quality**

#### Behavioral Prescriber Segmentation (BPS)

- **Dynamic Prescribing Potential**
  - General environment
  - Personality of physicians
  - Conditions of practices

- **Permeability to Investments**
  - Relational style
  - Economical style
  - Scientific style

---

- The share of brand prescription is driven by physicians preference level...
- … which is enhanced by acting on the BPM: (1) brand attributes, (2) service quality and (3) corporate reputation

---

- The BPS optimizes investment efficiency by considering:
  1. Factors that drive the dynamics of prescriptions
  2. Prescribers’ personalities
  3. Prescribers’ permeability to investments

---

*Smart Pharma Consulting* has developed methods and tools to gather each physician opinion on the 3 components of the Brand Preference Mix and information regarding the 3 dimensions of the Behavioral Prescriber Segmentation.

---

Source: Smart Pharma Consulting

---

1. Developed by Smart Pharma Consulting (see position paper “Best-in-Class Pharma Marketers” on: www.smart-pharma.com) –  
2. By market (competitors + brand) and by brand –  
3. Medico-marketing-sales investments

---
The ELITE Program\(^1\) enables med reps to interact more efficiently with prescribers and to optimize the prescription share of the brands they promote.

**Sales force effectiveness studies**

Example of applications to Sales force effectiveness

The ELITE Program proposes an **holistic** and **practical** approach to **improve med reps efficiency and efficacy**

**The ELITE Program**

1. **Prescriber Insight**
   - Better Knowledge &
   - Better Understanding
   - TO
   - Better Convince

2. **Brand Preference Tactic**
   - Reputation
   - Med Reps
   - Brand
   - Services

3. **High Impact Interactions**
   - Face-to-face calls
   - Interactions
   - Medical meetings
   - Congresses symposiums

4. **Job Passion**
   - More & Better Work
   - Higher Performance
   - Job Passion

---

**Smart Pharma Consulting** has created a series of tools and indicators to measure the impact of the ELITE Program on physicians opinion and prescribing behavior, especially in terms of Brand Preference.

---

Source: Smart Pharma Consulting

\(^1\) Developed by Smart Pharma Consulting (see position paper “Best-in-Class Medical Reps” on: www.smart-pharma.com)
The “Market Analysis & Forecasting” masterclass has been designed for participants looking for robust and simple tools, and wishing to strengthen their analytical skills

**Masterclass**: Market Analysis & Forecasting Excellence

### Day 1: Market Analysis
- **9:00** Introduction to the masterclass
- **9:10** Review and discussion of analytical concepts, methods and tools sent to participants as a pre-read
- **10:30** Lecture by and discussion with an expert: “Review of the most advanced market analyses – Lessons from non pharma markets”
- **11:45** Break
- **12:00** Case study #1: Market & brand dynamics evaluation:
  - Stakeholders behaviors analysis
  - Key market drivers & barriers analysis
  - Sensitivity of brands to operational investments
  - From data analysis to decision making
- **13:00** Lunch
- **14:00** Case study #1: cont.
- **16:00** Break
- **16:15** Presentation of the case study outputs, discussion and agreement on key learnings
- **17:45** End of the 1st day

### Day 2: Forecasting
- **8:30** Introduction to the 2nd day
- **8:40** Review and discussion of sales forecasting concepts, methods and tools sent to participants as a pre-read
- **10:00** Break
- **10:15** Case study #2 part 1: Baseline & scenario building:
  - Historical trends evaluation
  - Determination of future events and of their impact
- **12:30** Lecture by and discussion with an expert: “What is the business value of sales forecasting?”
- **13:00** Lunch
- **14:00** Case study #2 part 2: Sales forecast modeling:
  - Patient-based forecasting
  - Lifecycle based forecasting (new, growing, mature)
- **15:30** Break
- **15:45** Presentation of the case study (parts 1 & 2) outputs, discussion and agreement on key learnings
- **16:45** Co-development with participants of key learnings
- **17:45** End of the masterclass

Source: Smart Pharma Consulting

1 Intra-company programs proposed both in English and in French

2 Health authorities, payers, physicians, pharmacists, patients, patient advocacy groups, competitors, etc.

3 Medico-marketing and sales
# Introduction
- Foreword
- International healthcare expenditure

## Section 1. The French healthcare system

### 1.1. Key stakeholders
- Mapping of key stakeholders
- Policy makers and regulators
- Overall reimbursement and pricing processes
- Parliament and Ministry of Health
- ANSM
- HAS (CEESP – CT)
- CEPS
- National and regional market access in a nutshell
- Market access – European comparisons
- Social Security and Complementary Health Insurance Systems
- National Health Insurance Fund instances
- Compulsory complementary health insurance plan
- Complementary health cover organizations
- National, regional and local organization of the Social Health Insurance System
- Regional health agencies
- Healthcare professionals and facilities
- Hospital funding systems
- Drug distribution channels
- Economy of retail pharmacies
- Voluntary trade organizations
- On-line sales of pharmaceutical products
- Patients confidence in drugs

### 1.2. Recent reforms
- The French Sunshine Act
- LFSS 2014: New regulations towards generics and biosimilars
- LFSS 2015 key articles regarding drugs and pharma companies
- LFSS 2016 key articles regarding drugs and pharma companies
- Health System Modernization Act (incl. GHT)
- LFSS 2017 key articles regarding drugs and pharma companies
- LFSS 2018 key articles regarding drugs and pharma companies
- “My Health 2022”: Territorial reorganization of care project
- LFSS 2018 main saving measures
- LFSS 2019 main savings measures
- LFSS 2019 key articles regarding drugs and pharma companies
- The future of GAFA / Telemedicine

### 1.3. Healthcare expenditure
- Relation between healthcare expenditure and GDP
- Supply, consumption and funding of healthcare
- Breakdown of healthcare expenditure and coverage
- Social Security & national health insurance fund balances
- ONDAM
- Hospital expenses
- Expenditure by age group
- Evolution of the reimbursement system
- Price cuts and economic impact
- Main governmental measures relative to generics and biosimilars
- Drivers and limiters of the OTC market

---

### Global pharma market (2018 – 2023)
Section 2. The French pharmaceutical market

2.1. Evolution of drugs sales  p. 225

- Classification of pharmaceutical products in France
- Evolution of drugs sales by segment (2013 – 2018)
- Hospital market dynamics (2013 – 2018)
- Evolution of drugs sales by reimbursement rate (2013 – 2018)
- Top 10 therapeutic areas retail & hospital (2018)
- Top 10 products retail & hospital (2018)
- Generics penetration (1999 – 2018)
- Evolution of reimbursable generics in the retail market
- Molecules having lost their patent protection in 2018
- Savings generated by generics (2013 – 2018)
- OTC market size and structure (2018)
- Top 10 therapeutic areas in the OTC market (2018)
- Top 10 brands and umbrella brands in the OTC market (2018)
- Sales of drugs on top of T2A (2013 – 2018)

2.2. Evolution of pharma companies sales  p. 253

- Top 10 pharma companies retail and hospital markets (2018)
- Top 10 pharma companies on the retail market (2018)
- Top 10 pharma companies on the hospital market (2018)
- Top 10 generics companies on the retail market (2018)

2.3. Future market trends  p. 261

- Factors driving the evolution of drugs sales by market segment (2019 – 2023)
- Drugs sales forecast by segment (2019 – 2023)
# Section 3. Strategic priorities for pharma companies

<table>
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<tr>
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**Executive Summary**

**Glossary**
This report analyzes the current situation and the key trends on the French Pharma market by the end of 2023 to provide pharma companies with key strategic insights

**2019 – 2023 French pharma market prospects & strategic implications**

- Despite an ever-tougher environment, the French pharma market should remain a key priority for pharma groups
- Smart Pharma Consulting proposes to address the following key issues related to the French healthcare system and pharma market evolution by the end of 2023, to better grasp its strategic impacts for pharma companies

- How is the French healthcare system organized at national and regional levels?
- What are the key recent measures introduced by health authorities and their impact?
- What are the behavioral trends of key stakeholders and their impact by 2023?
- What are the estimated sales forecasts by strategic segment on the French pharma market by 2023?
- What could be the strategic and organizational implications for pharma companies by 2023?
Healthcare expenditure will keep on growing faster than national economies due to demographic factors and willingness of citizens to have better access to healthcare.

**Healthcare expenditure as a percentage of GDP (2017*)**

- Healthcare expenditure represents one of the largest public spending items in most developed economies: 1\textsuperscript{st} (USA), 2\textsuperscript{nd} (France, Germany, Japan, and UK)\textsuperscript{1} and 3\textsuperscript{rd} (Italy and Spain)\textsuperscript{2}
- At best, governments and payers will manage to slow down the rise of healthcare expenditure as a percentage of GDP but would not be able to stop it, mainly for demographic reasons
- There is no optimal ratio of healthcare expenditure over GDP, it primarily results from:
  - Public health conditions
  - Governments investment prioritization
  - Citizens willingness to seek for care
  - Healthcare cost

*Note: Data 2015 (USA and Japan)


\textsuperscript{1} After social protection – \textsuperscript{2} After social protection and general public services
By 2023, the sales growth of the pharma market should be mainly driven by generics and biotech originators, but pharma companies should lose two points of profitability.

Global pharmaceutical market growth by strategic segment (2018 – 2023)

- By 2023, the pharma market sales (incl. human drugs only for the non-OTC segments; medical devices and food supplements for the OTC segment) should reach USD 1,556 B and grow at a pace of +5% p.a.
- The average EBITDA of the Pharma industry should decrease from ~32% in 2018 to ~30% in 2023, mainly as a result of increasing pressure on price.
- The OTC segment appears to be the least attractive.
- The biotech segment will remain attractive but biosimilar competition will ramp up.

By 2023, the pharma market sales (incl. human drugs only for the non-OTC segments; medical devices and food supplements for the OTC segment) should reach USD 1,556 B and grow at a pace of +5% p.a.

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The OTC segment appears to be the least attractive.

The biotech segment will remain attractive but biosimilar competition will ramp up.

Sources:
IQVIA Institute (January 2019) – Global OTC Drugs Market, Mordor Intelligence (May 2018) – Smart Pharma Consulting estimates

1 Including branded and unbranded generics and biosimilars, excluding OTC – 2 Excluding biosimilars, already included in the “Generics” segment – 3 Earnings before interest, taxes, amortization and depreciation
Stakeholders in the French healthcare system can be divided according to their role as decision makers, payers, providers / suppliers or consumers.

### Mapping of key stakeholders

- **Parliament**
  - Votes on laws
  - Introduces bills (draft laws) in Parliament

- **Government**
  - Ministries for Health
  - Ministries for Economy
  - Other Ministries

- **ANSM**
  - Supervises
  - Grants marketing authorization

- **CEPS**
  - Sets prices

- **HAS**
  - Organizes the healthcare offer
  - Delivers opinions

- **Pharma companies**
  - Sell drugs to pharmacists
  - Sell drugs to hospitals
  - Collaborate

- **Healthcare professionals**
  - Deliver services / Sell drugs

- **Hospitals**
  - Deliver services

- **PAGs**
  - Patients
  - Households

- **Payers**
  - Social health insurance
    - **UNCAM**
  - Complementary health insurance
    - **UNOCAM**

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Sources: Smart Pharma Consulting analyses

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1 The exact name of this ministry is: Ministry of Solidarity and Health
2 The exact name of this ministry is the Ministry for the Economy and Finance which includes the budget and the industry
In France, various healthcare institutions are involved in the setting of the price and reimbursement rate after a drug has received its marketing authorization

**Overall reimbursement and pricing processes**

<table>
<thead>
<tr>
<th>ANSM / EMA</th>
<th>HAS</th>
<th>CEESP</th>
<th>Social Health Insurance</th>
<th>CEPS</th>
<th>UNCAM</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Retail</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No request for reimbursement</td>
<td>Request for reimbursement</td>
<td>Medico-technical evaluation of <strong>clinical benefit</strong> (SMR) and of <strong>clinical benefit improvement</strong> (ASMR)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unfavorable opinion</td>
<td>ASMR IV (leading to treatment &amp; savings in costs)</td>
<td>ASMR I, II, III</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-reimbursable drug</td>
<td>Reimbursable drug</td>
<td>Economic assessment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Free price</strong> (no negotiation with CEPS)</td>
<td>Price Negotiation (or unilateral price setting) based on ASMR</td>
<td>Reimbursement rate validated by UNCAM based on SMR</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Registration on the Social Security list</td>
<td></td>
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<tr>
<td>Commercialization</td>
<td></td>
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</tr>
</tbody>
</table>

| Hospital | |
| Application for approval for hospital only use | |
| ASMR IV & V | Drugs evaluated as bringing minor or no clinical added value vs. existing offering |
| Retrocession drug list²,³ | Expensive drug list³ |
| Setting of a reference price | Inclusion in GHS⁴ |
| Free price | |


¹ After a favorable opinion of the MA commission (national level) or the EMA (European level) – ² These drugs can be dispensed to outpatients by hospital pharmacies – ³ The cost of these drugs is not covered by the hospital but by the Social Health Insurance – ⁴ Similar to Diagnosis-related groups (DRGs)
Managed entry agreements may be considered by the CEPS when the level of medical evidence is too low and/or the financial impact is too high

CEPS – Options for a newly approved product

- **Reimbursement with no additional evidence**
  - Payers estimate that the adequate level of evidence is provided to cover the drug

- **Reimbursement with managed entry agreements**
  - Payers have uncertainties regarding evidence provided by the company

- **No reimbursement**
  - The manufacturers have the option to reapply with more evidence

**Decision of reimbursement**

**Managed entry agreement**

- **No contract**
  - Outcomes-based contract
    - Payers have uncertainties regarding the medical outcomes / cost-effectiveness of the drug
  - Financially-based contract
    - Payers have uncertainties regarding the budgetary impact of the drug
  - No contract

The implementation of managed entry agreements are most often time-consuming and costly for payers and/or pharma companies, outweighing their benefits

### CEPS – Pros & Cons of managed entry agreements

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Potential to <strong>re-evaluate</strong> the effectiveness of drugs at a later stage and <strong>re-negotiate</strong> the price based on real-world evidence</td>
<td>▪ <strong>Additional efforts</strong> required to make a new drug available to patients, such as negotiation time, monitoring of patient response, data gathering, development of registries, etc.</td>
</tr>
<tr>
<td>▪ Help <strong>address post-licensing uncertainty</strong> by offering flexibility in dealing with new and often expensive treatments</td>
<td>▪ Threat that manufacturers could start proposing <strong>higher entry prices</strong> in the expectancy of having to engage managed entry agreements</td>
</tr>
<tr>
<td>▪ Improve the <strong>cost-effectiveness</strong> through a <strong>discount</strong> or a <strong>payback</strong> agreement for non-responders</td>
<td>▪ <strong>Limited capacity</strong> to implement and assess evidence, notably if implementation takes place at regional/hospital level</td>
</tr>
<tr>
<td>▪ Enable different types of schemes addressing different needs, both <strong>financial</strong> and <strong>non financial</strong></td>
<td>▪ <strong>Costs</strong> related to the implementation of the managed entry agreement can, in some cases, totally <strong>outweigh benefits</strong></td>
</tr>
<tr>
<td>▪ Speed up <strong>pricing</strong> negotiations and <strong>reimbursement</strong></td>
<td>▪ <strong>Concessions</strong> required such as refunds for non-respondent patients, discounts, gathering of additional data</td>
</tr>
<tr>
<td>▪ Potential to benefit from a better <strong>corporate reputation</strong> as a result of the willingness to take responsibility for the use of the drug in real-life</td>
<td>▪ Voluntary versus no voluntary nature of such contracts leading to a <strong>variability in stakeholders perception</strong></td>
</tr>
<tr>
<td>▪ Potential to <strong>reinforce</strong> the long-term collaboration between payers, health authorities and pharmaceutical companies</td>
<td></td>
</tr>
<tr>
<td>▪ Enable <strong>discounts</strong> without impacting list prices</td>
<td></td>
</tr>
</tbody>
</table>

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Sources: “Managed entry agreements for pharmaceuticals: the European experience”, Alessandra Ferrario and Panos Kanavos, April 2013 – Smart Pharma Consulting analyses
The price level accepted by the CEPS (Economic Committee on Healthcare Products) depends on the level of ASMR granted by the Transparency Committee

### CEPS – Price setting for reimbursable ambulatory drugs

#### Rating of ASMR
- **ASMR I to III** (significant improvement)
- **ASMR IV** (Minor improvement)
- **ASMR V** (No improvement)

#### Pricing principles
- **Consistent pricing** with prices in four other major European markets
- **No increase** in the cost of medical treatment

#### Savings in the cost of medical treatment
- **Referent**: Comparator used by the CT during its evaluation or, in the case of a product line extension, the cheapest competitors
- **Level of price reduction**:
  - **Low**: If it is considered that the new product will only take part of the market of other products already in the market
  - **High**: If it is estimated that the new product may increase consumption

Specific clauses may be added to the price agreement between the CEPS and the pharma companies:

- **Risk sharing clause**: The company is bound to pay financial compensation by refunding any excess costs to the Health Insurance if sales exceed those forecasted for the first four years after launch

- **Price revision clauses**:
  - **Volume clauses**: are used when the ASMR for a drug has only changed for one of its indications; here sales volumes are monitored to make sure the product is used in-label. If these volume clauses are not respected, prices will be lowered or a rebate due from the companies
  - **Cost clauses for daily dosages**: these clauses are used when there is a range of dosages; 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 forecasted, the price is revised in order to re-establish the daily treatment cost which was forecasted initially
  - **Dosage or posology clauses**: the treatment cost is initially calculated based on the average dose; these clauses result in a price reduction if the average stated dose is exceeded

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**Sources:** CEPS 2015 annual report (Appendix 4), published in 2016 – Smart Pharma Consulting analyses

1. Apply to the initial registration of drugs – 2 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 price per pack or on the daily treatment cost for chronic diseases
The criteria for the inclusion of a hospital drug on the list for invoicing on top of “T2A” are well defined since March 2016

--- Criteria for inscription on/radiation from the list on top of T2A expensive hospital drugs ---

<table>
<thead>
<tr>
<th>Criterion n°1</th>
<th>The drug must be mainly used in the hospital setting</th>
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<tbody>
<tr>
<td></td>
<td>The drug must be mainly used in the hospital setting</td>
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<tr>
<td></td>
<td>If it is not the case, the CEPS considers that its cost can be funded under the hospital service tariffs (T2A system)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Criterion n°2</th>
<th>The drug must provide an important Clinical Benefit (important SMR)</th>
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<tr>
<td></td>
<td>The drug must provide an important Clinical Benefit (important SMR)</td>
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<tr>
<td></td>
<td>Suggesting that the drug has a positive risk/benefit ratio and that it covers an actual medical need</td>
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<table>
<thead>
<tr>
<th>Criterion n°3</th>
<th>The drug must provide a significant Clinical Added Value (ASMR I to III)</th>
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<td></td>
<td>The drug must provide a significant Clinical Added Value (ASMR I to III)</td>
</tr>
<tr>
<td></td>
<td>Suggesting that the drug is innovative vs. available alternatives</td>
</tr>
<tr>
<td></td>
<td>An exception can be made for products with ASMR IV with no therapeutic alternatives</td>
</tr>
<tr>
<td></td>
<td>For equity reasons, when a product receives an ASMR IV or V and its comparators are already listed, the product will also be listed, despite its poor ASMR</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Criterion n°4</th>
<th>The cost of the drug is incompatible with the T2A system</th>
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<tbody>
<tr>
<td></td>
<td>The cost of the drug is incompatible with the T2A system</td>
</tr>
<tr>
<td></td>
<td>The threshold is fixed at a cost of the drug representing &gt; 30% of the GHS (as set under the hospital service tariffs for a given disease)</td>
</tr>
</tbody>
</table>

--- Criteria for radiation of the list ---

When a product does not meet inclusion criteria anymore, it may be excluded:

- When there is a reevaluation by the transparency committee of the HAS of the SMR / ASMR
- When prices have decreased enough to make the product compatible with the T2A system

--- Sources ---

Sources: Decree of March 25th, 2016 regarding modalities of inscription to the “liste en sus” – Smart Pharma Consulting analyses

--- Note ---

¹ Activity-based costing system similar to a Diagnosis related group-based funding
When the second generics company enters the market, the pricing strategy becomes even more aggressive

**CEPS – Hospital generics pricing: Zolendronic acid (Zometa)**

- Zometa, marketed by Novartis, is a bisphosphonate used in:
  - The prevention of bone complications in adult patients with advanced malignant disease
  - The treatment of tumor-induced hypercalcemia in adult patients
- The first generic, marketed by Sandoz, entered the market mid-May 2013, a week before Mylan. Fresenius launched its 4 mg version in June, Pfizer in May and Medac in August
- Competition on price is usually even more aggressive in hospitals when there are more than one company marketing the generic
- However, according to a representative from a generics company interviewed: "This behavior is illogical and is prejudicial for all generics companies as this price does not support the market and does not permit us to offer associated services"

**Comments**

Sources: Business Intelligence – Smart Pharma Consulting analyses
In France, pharma companies and patients must wait almost 17 months after marketing authorization to get a new drug reimbursed and launched\(^1\)

**Average time to market – European comparisons**

- In Europe, the delay between marketing authorization of a drug and its availability on the market may vary widely, due to the time required to obtain its inclusion on reimbursement list and a price agreement.
- In countries such as France, Italy or Spain, this delay exceeds the 180 days recommended by the European Commission.
- An important delay may be harmful both for patients who do not have full access to innovative therapies and for companies which face a loss of revenues\(^1\).
- The UK and Germany have no delay since the price and reimbursement negotiations occur once the product has reached the market.
- In 2018, the LEEM (French association of pharmaceutical companies) has carried out a study on 67 new products, showing an average time between marketing authorization and price & reimbursement of 563 days.

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\(^1\) Excluding early access programs for breakthrough innovations (e.g. ATU in France) – \(^2\) For drugs receiving their first marketing authorization between 2013 and 2015.

Sources: Patients W.A.I.T Indicator – EFPIA (March 2018) – Smart Pharma Consulting analyses

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Median time in days between marketing authorization and price and reimbursement\(^1,2\)
Drugs sold in retail pharmacies are mainly sourced from wholesalers / distributors, while hospital drugs are usually directly sourced from pharmaceutical companies.

**Drug supply chain (2018)**

Total pharmaceutical market\(^1\) ~€ 27.7 B

- ~250 pharmaceutical companies
  - 59.6% (~€ 16.5 B)
- 7 wholesalers - distributors
  - 59.2% (~€ 16.4 B)
- 22,082 pharmacies\(^2\)
  - 74.4% (~€ 20.6 B)
- 3,044 healthcare facilities\(^3\)
  - 25.6% (~€ 7.1 B)

---


\(^1\) Ex factory-price, including hospital rebates – \(^2\) ~70% belonging to Voluntary Trade Organizations – \(^3\) Public and private
The revision of the smoothed digressive margin is part of a decorrelation process between the economy of retail pharmacies and the price of reimbursed drugs.

11th amendment to the National Pharmaceutical Agreement

- The main priority of the 11th amendment to the National Pharmaceutical Agreement is to change the remuneration of retail pharmacies and make them less dependent on the price and volume of reimbursable drugs.
- Thus, it proposes progressive transfer to new forms of remuneration related to dispensing and to the improvement of patients management.

### Evolution of the Smoothed Digressive Margin on Ex-factory Price

<table>
<thead>
<tr>
<th>Year</th>
<th>0%</th>
<th>6%</th>
<th>8.5%</th>
<th>10%</th>
<th>13%</th>
<th>21%</th>
<th>25.5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>2018</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>2019</td>
<td>0.0%</td>
<td>6.0%</td>
<td>6.0%</td>
<td>6.0%</td>
<td>10.0%</td>
<td>13.0%</td>
<td>21.4%</td>
</tr>
<tr>
<td>2020</td>
<td>0.0%</td>
<td>5.5%</td>
<td>7.0%</td>
<td>10.0%</td>
<td>13.0%</td>
<td>21.4%</td>
<td>25.5%</td>
</tr>
</tbody>
</table>

### New Dispensing Fees

<table>
<thead>
<tr>
<th>Description</th>
<th>2019</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fees for the delivery of a prescription</td>
<td>€0.50</td>
<td>€0.50</td>
</tr>
<tr>
<td>Fees related to the age of the patient (youth children and elderly people)</td>
<td>€0.50</td>
<td>€1.55</td>
</tr>
<tr>
<td>Fees for the delivery of specific drugs (e.g. immunosuppressive drugs)</td>
<td>€2.00</td>
<td>€3.50</td>
</tr>
</tbody>
</table>

### New Missions

<table>
<thead>
<tr>
<th>Description</th>
<th>Remuneration (2019)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication reports for elderly people taking more than 5 drugs</td>
<td>€60 for the initial interview and then €30 or €20</td>
</tr>
<tr>
<td>Belonging to a primary care team</td>
<td>€420 per year</td>
</tr>
<tr>
<td>Share medical file</td>
<td>€1 per medical file opened</td>
</tr>
</tbody>
</table>

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1 VAT excluded  
2 Amount from which the margin is capped: €1,500 in 2017, €1,515 in 2018, €1,600 in 2019, and €1,930 in 2020. 
3 The amendment was signed by only one of the three French pharmaceutical unions. 
4 Whether new treatments are initiated in subsequent years or not.
The LFSS 2019 introduced new measures at physician and patient level to increase the substitution rate and thus the level of generics penetration

**LFSS 2019: New measures to boost generics penetration**

Generics penetration rate in volume in the retail reimbursable market

- In 2018, generics accounted for 37.3% of the total reimbursable retail market in volume (and 18.9% in value)
- To foster the generics penetration rate, the LFSS 2019 introduced:
  - The obligation for physicians to indicate on their prescription the medical reason why they refuse substitution, if they want to do so
  - The reimbursement limitation of a genericized brand based on the generics price, if patients refuse substitution
  - If the generics penetration rate were 100% of the exploited Directory, generics would account for 46% of the total reimbursable retail market in volume...
  - … while the average within the OECD countries is above 50% (e.g. 85% in the UK or 81% in Germany)

Sources: GERS data – GEMME – LFSS 2019 – Smart Pharma Consulting analysis

1 Implementation starting in January 2020  
2 Generic directory of the ANSM
In 2017, total expenditure for healthcare goods and services amounted to €199.3 billion (of which ~47% from hospitals) and was mostly funded by the Social Security.

Supply, consumption and funding of healthcare and medical goods

**Patients**

- **Suppliers**
  - Hospitals: 46.6%
  - Primary care: 26.8%
  - Retail pharmacies: 16.3%
  - Patients transport: 2.5%
  - Others¹: 7.8%

- **Consumers**
  - Healthcare goods and services expenses in 2017: €199.3 billion
  - 77.8%: National Health Insurance Fund
  - 7.5%: CMU / AME²
  - 3.7%: Mutual Insurance Funds
  - 7.0%: Private Insurance companies
  - 2.5%: Provident Institutions

- **Payers**
  - Households³: 46.6%
  - Employers: 45.5%
  - Salaried and Households: 45.3%
  - Public administration: 9.2%
  - Employers: 55%
  - Salaried and Households: 45%

**Financial Sources⁴**

1. Optics, prostheses, small devices, hygiene and first aid, etc.
2. CMU / AME: “Couverture Médicale Universelle Complémentaire / Aide Médicale d’Etat”: Complementary universal medical coverage / State medical assistance
3. Non reimbursed, deductible, etc.
4. 2015 data

Sources: « Les dépenses de santé en 2017 - Résultats des comptes de la santé » (September 2018), DREES – Smart Pharma Consulting analysis
Humira remains the leader of the French retail market while Imbruvica entered the top 10 list, moving from the 50th in 2017 to the 7th position in 2018.

Top 10 products in value – Retail sales (2018)

- **Humira**: €434 M
- **Lucentis**: €364 M
- **Eylea**: €286 M
- **Xarelto**: €271 M
- **Eliquis**: €261 M
- **Doliprane**: €243 M
- **Imbruvica²**: €191 M
- **Xtandi**: €186 M
- **Zytiga**: €179 M
- **Ibrance³**: €171 M

12.5% of the retail market
Total market: €20.6 B

Average turnover = €258 M

Sources: GERS – Smart Pharma Consulting analyses

- **Market share**
  - Humira: 2.1%
  - Lucentis: 1.8%
  - Eylea: 1.4%
  - Xarelto: 1.3%
  - Eliquis: 1.3%
  - Doliprane: 1.2%
  - Imbruvica²: 0.9%
  - Xtandi: 0.9%
  - Zytiga: 0.9%
  - Ibrance³: 0.8%

- **2017 ranking**
  - 1 = Humira
  - 2 = Lucentis
  - 3 = Eylea
  - 4 = Xarelto
  - 7 = Eliquis
  - 5 = Doliprane
  - 50 = Imbruvica²
  - 8 = Xtandi
  - 15 = Zytiga
  - N/A = Ibrance³

- **2017 - 2018 evolution**
  - +0.9% = Humira
  - +15.3% = Lucentis
  - +16.2% = Eylea
  - +12.4% = Xarelto
  - +42.4% = Eliquis
  - +1.5% = Doliprane
  - +220.1% = Imbruvica²
  - +9.3% = Xtandi
  - +26.0% = Zytiga
  - N/A = Ibrance³

*Rise - : Drop - : No change in 2018 vs. 2017 ranking*

1 Constant ex-factory prices excluding rebates and taxes – ² Progressively transferred from the hospital to the retail market, since August 2017 – ³ Progressively transferred from the hospital to the retail market from March 2018
In 2018, the self-medication market accounted for 5.0% of the retail pharmaceutical market and included both reimbursable and non-reimbursable non-prescribed drugs.

**OTC market size and structure (2018)**

- **Self-medication market**
  - 5.0% (€ 1.0 B)
  - Non-prescribed OTC
    - (i.e. non prescription-bound non-reimbursable drugs)
    - 4.1% (€ 0.8 B)
  - Non-prescribed OTX (i.e. non prescription-bound reimbursable drugs)
    - 0.9% (€ 0.2 B)
  - Prescribed OTX (i.e. non-prescription-bound reimbursable drugs)
    - 6.6% (€ 1.4 B)

- **Total pharmaceutical retail market**
  - (Manufacturer prices excl. tax)
  - € 20.6 B

- **OTC market** (prescribed or not)
  - 7.6% (€ 1.6 B)
  - Prescribed OTC
    - (i.e. non-prescription-bound non-reimbursable drugs)
    - 3.5% (€ 0.7 B)
  - Strictly defined OTC
  - Non-prescribed OTC
    - (i.e. non prescription-bound non-reimbursable drugs)
    - 4.1% (€ 0.8 B)

- **Reimbursable/non-reimbursable**
  - prescription-bound drugs
    - (either prescribed or not)
    - 84.9% (€ 17.5 B)

**Sources:** Smart Pharma Consulting estimates based on GERS and IQVIA (Pharmastat) data


2.1. Evolution of drugs sales

- The strictly defined OTC market accounts for **82% of the self medication market**
- OTX or semi-ethical drugs (non-prescription-bound, reimbursed only if prescribed) are massively prescribed by physicians (sometimes on patient request), which limits the growth of the reconstituted self-medication sales
In 2018, the decrease of on top of T2A drugs sales vs. 2017 was mainly due to the transfer of classes of products (e.g. hepatitis C) from the hospital to the retail market

Sales of on-top of T2A drugs (2013 – 2018)

- In 2018, the decrease by 8.0% of on-top of T2A drugs sales vs. 2017 was explained by the transfer of classes of drugs from the hospital to the retail market (e.g. hepatitis C drugs, whose transfer was decided on March 29th, 2018 and effective since April 2nd, 2018)
- In 2018, 6 drugs reached hospital sales above € 100 M:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Therapeutic class</th>
<th>2018 sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revlimid Celgene</td>
<td>Other antineoplastics</td>
<td>€ 266 M</td>
</tr>
<tr>
<td>Lovenox Sanofi</td>
<td>Fractionated heparins</td>
<td>€ 160 M</td>
</tr>
<tr>
<td>Epclusa Gilead</td>
<td>Hepatitis C antivirals</td>
<td>€ 153 M</td>
</tr>
<tr>
<td>Darzalex J&amp;J</td>
<td>Monoclonal antibody antineoplastics</td>
<td>€ 147 M</td>
</tr>
<tr>
<td>Imnovid Celgene</td>
<td>Other antineoplastics</td>
<td>€ 142 M</td>
</tr>
<tr>
<td>Remicade MSD</td>
<td>Anti-TNF</td>
<td>€ 110 M</td>
</tr>
</tbody>
</table>

Expensive drugs not funded under the hospital service tariffs: +2.2% vs. 2017

Sources: GERS dashboards – Smart Pharma Consulting analyses

1 Excluding new hepatic antiviral drugs accounting for € 1,096 in 2014 – 2 Drugs retroceded that can also be delivered in retail pharmacies (e.g. hepatic antiviral drugs, anti-HIV drugs, some oncology products) – 3 Ex-factory price, excluding rebates and taxes
In 2018, Biogaran, Pfizer and Sandoz generated more than €100 M sales and represented together ~82% of the French biosimilars market in value.

**Top 10 companies on the biosimilars market – In value**

- **Biogaran**: €172 M
- **Pfizer**: €137 M
- **Sandoz**: €129 M
- **Biogen**: €47 M
- **Lilly**: €18 M
- **Teva**: €17 M
- **Gedeon Richter**: €10 M
- **Actavis / Arrow**: €3 M
- **MSD**: €2 M
- **Amgen**: €2 M

**Average turnover = €54 M**

**Total market**: €0.5 B

**Market share**

- Biogaran: 32.0%
- Pfizer: 25.4%
- Sandoz: 24.1%
- Biogen: 8.7%
- Lilly: 3.3%
- Teva: 3.2%
- Gedeon Richter: 1.9%
- Actavis / Arrow: 0.6%
- MSD: 0.4%
- Amgen: 0.4%

**Biosimilars weight in the portfolio**

- Biogaran: +277.5%
- Pfizer: +7.2%
- Sandoz: +46.4%
- Biogen: +277.4%
- Lilly: +161.9%
- Teva: +11.3%
- Gedeon Richter: +38.6%
- Actavis / Arrow: +311.4%
- MSD: N/A
- Amgen: N/A

**2017-2018 evolution**

- Biogaran: +38.6%
- Pfizer: +277.4%
- Sandoz: +161.9%
- Biogen: +11.3%
- Lilly: +277.4%
- Teva: +7.2%
- Gedeon Richter: +46.4%
- Actavis / Arrow: +277.5%
- MSD: N/A
- Amgen: N/A

**Sources**: GERS – Smart Pharma Consulting analyses

1 Both retail and hospital sales – 2 Ex-factory price, excluding taxes and rebates – 3 Acquired by Teva on August 2nd, 2016
By 2023, the French pharmaceutical market should be mainly driven by innovative hospital products and biosimilars

**Drugs sales forecast by segment (2013 – 2018 – 2023)**

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Market</th>
<th>Hospital sales</th>
<th>Not reimbursed</th>
<th>Reimbursed</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>€25.9 B 1</td>
<td>€5.5</td>
<td>€2.1</td>
<td>€13.3</td>
</tr>
<tr>
<td>2018</td>
<td>€27.7 B 1</td>
<td>€7.1</td>
<td>€3.5</td>
<td>€13.3</td>
</tr>
<tr>
<td>2023</td>
<td>€29.2 B 1</td>
<td>€8.1</td>
<td>€3.7</td>
<td>€13.2</td>
</tr>
</tbody>
</table>

**CAGR**

<table>
<thead>
<tr>
<th>Period</th>
<th>2014-2018</th>
<th>2018-2023</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Market</td>
<td>+1.4%</td>
<td>+1.0%</td>
</tr>
<tr>
<td>Hospital sales</td>
<td>+5.3%</td>
<td>+2.5%</td>
</tr>
<tr>
<td>Not reimbursed</td>
<td>+0.5%</td>
<td>+1.5%</td>
</tr>
<tr>
<td>Reimbursed</td>
<td>+23.5%</td>
<td>+25.3%</td>
</tr>
</tbody>
</table>

**Sources:** GERS dashboards – Smart Pharma Consulting estimates

1 Constant ex-factory prices – 2 Estimated rebated sales including hospital sales of biosimilars, products invoiced in addition of the hospitalization charges (on top of T2A) and reassigned medicine sales – 3 Reimbursable generics and quasi-generics – 4 Sales of drugs whose patents have not expired and of other specific products (calcium, sodium, potassium, paracetamol, etc.) – 5 Compound Annual Growth Rate
Pharmaceutical companies strategic priorities by 2023 will be linked with the behavior of the “7 Ps” stakeholders

7Ps

Policy makers

Pharma competitors

Physicians

Pharma company

Patients & PAGs

Payers

Sources: Smart Pharma Consulting estimates

1 Pharmacists also play the role of purchasers and their importance will keep on increasing in the upcoming years, either on the open care or the hospital segments
Policy makers & Payers will work jointly to secure the sustainability of the healthcare system, implying its redesign and the introduction of new measures and new taxes

Stakeholder behavioral trends: Policy makers & Payers (1/4)

<table>
<thead>
<tr>
<th>2019 – 2023 Trends</th>
<th>Driving factors</th>
<th>Implications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global cost optimization</td>
<td>▪ Ageing of population associated to low economic growth leading to larger deficits over the 2019-2023 period, and beyond</td>
<td>▪ Increase of the CSG and possibility to introduce new taxes to reduce dependency on social contributions and thus, on the employment</td>
</tr>
</tbody>
</table>
| ▪ Research of new funding mechanisms to ensure a better sustainability of the healthcare system | ▪ ~2/3 of healthcare expenditure covered by the National Health Insurance Fund, whose revenues are generated by social contributions | ▪ Redesign of the healthcare system:  
  – Shift from hospital to home care  
  – Improve hospital / open care markets coordination  
  – Improve patient journey efficiency  
  – Set up a new framework for funding innovation in the healthcare system¹ |
| ▪ Reorganization of the healthcare system to improve its efficacy and efficiency | ▪ French GDP expected to grow by 1.6% p.a. until 2023 | ▪ Introduction of measures and tools:  
  – Tighter control of hospital costs  
  – Increase price pressure on reimbursed drugs  
  – Reinforcement of the ROSP² contracts plan for physicians  
  – Limit access to ALD³  
  – Budgeting control generalization |
| ▪ Reduction / prevention of National Health Insurance Fund deficit | ▪ National Health Insurance Fund cumulated deficit reaching a total of €120 B over the 2008-2017 period | |
| ▪ Capping of the mid to long term healthcare expenditure objective by the government at ≤ +2.3% p.a. on average by the end of 2023 | ▪ Willingness of the government to reduce the national public deficit close to 3.0% of the GDP as per EU objective (2.6% has been reached in 2018, but 3.2% is expected for 2019) | |

Sources: Smart Pharma Consulting analyses

¹ As addressed in the Article 51 of the LFSS 2018  
² Bonus program to encourage physicians to comply with "best prescribing practices" for a better efficacy/cost ratio  
³ 100% cost coverage for chronic and long-lasting diseases
Pharma companies must position their products, services and themselves to be perceived by Policy makers and Payers as offering superior value than competition

**Strategic priorities induced by Policy makers & Payers behavioral trends**

<table>
<thead>
<tr>
<th>Behavioral trends</th>
<th>Strategic priorities for pharma companies</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Stricter control of reimbursed drug expenditure</td>
<td>Enhance the global value proposition (incl. corporate identity, product and service offering) through:</td>
</tr>
<tr>
<td></td>
<td>- Dedicated corporate reputation programs targeted at policy makers and government</td>
</tr>
<tr>
<td></td>
<td>- Generation of RWD (Real Word Data) and …</td>
</tr>
<tr>
<td></td>
<td>- ... high quality medico-economic studies (whenever relevant)</td>
</tr>
<tr>
<td></td>
<td>- Initiation / support of specific projects to improve patient care</td>
</tr>
<tr>
<td>2. Measures to boost generics &amp; biosimilars</td>
<td>Participate to working groups with health authorities and other stakeholders to:</td>
</tr>
<tr>
<td></td>
<td>- Facilitate the change management</td>
</tr>
<tr>
<td></td>
<td>- Ensure this change will have a positive, or at least a neutral effect, on pharma company performance</td>
</tr>
<tr>
<td>3. Shift from hospital to ambulatory care</td>
<td>Increase or maintain R&amp;D activities in France to be in a more favorable position vis-à-vis health authorities to get reimbursement and to negotiate price of drugs</td>
</tr>
<tr>
<td>4. Promotion of R&amp;D investments in France</td>
<td></td>
</tr>
</tbody>
</table>

Sources: Smart Pharma Consulting analyses
Succeeding on the French Biosimilars Market

Everything you wanted to know!

Position Paper

June 2019
This position paper provides key information and analyses to evaluate the French biosimilars market dynamics and the key success factors for pharma companies.

**Context & objectives**

- Sandoz, Teva or Hospira (Pfizer), which have pioneered the biosimilars market in France, have placed great hopes in its development.

- However, 12 years down the road, the achievement of these precursors and of the followers can be regarded as somewhat below expectations.

- **Smart Pharma Consulting**, which has developed a robust experience at analyzing and advising pharma companies on the biosimilars market, proposes to:

  1. Analyze the biosimilars market structure and dynamics
  2. Review the French regulatory environment
  3. Share insights regarding customers behaviors
  4. Evaluate the competitive landscape and the key success factors
  5. Estimate 2018 – 2023 market growth
The biosimilars development on the French market is driven by the prescription of physicians who are encouraged by health authorities and certain hospital managers.

**Stakeholders involved in the French biosimilars market**

Health Authorities & Payers

- Health authorities and payers have introduced a series of measures to convince hospital and office-based physicians to prescribe more biosimilars, either as an initial treatment or as a switch.
- The Ministry of Health has set the objective of achieving 80% biosimilar penetration by 2022.

- Physicians prescription of biosimilars is very different according to the product considered.
- Hospital pharmacists play a role in purchasing.

- Patients and PAGs are still wary regarding the prescription of biosimilars.
- They want to be informed in a transparent manner.

- Retail pharmacists are divided regarding the substitution of biological drugs.

Office

- Physicians

Hospital

- Pharmacists
- Physicians

Rx

Dispensation

Patients

Retail pharmacists

† National Health Insurance Fund
Biosimilars, whose first products were launched in France in 2007, accounted for a total of € 538 M in 2018, based on ex-factory prices excluding rebates and taxes.


Sources: GERS – Smart Pharma Consulting analyses

1 Ex-factory prices excluding rebates and taxes – 2 Compound annual growth rate
When considering the rebates granted to hospitals on list prices, the 2018 biosimilars market reached €358 M and the hospital sales are reduced to 46% of the total.


<table>
<thead>
<tr>
<th>Year</th>
<th>Hospital</th>
<th>Retail</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>1 M³</td>
<td>4 M</td>
</tr>
<tr>
<td>2008</td>
<td>4 M</td>
<td>22 M</td>
</tr>
<tr>
<td>2009</td>
<td>12 M</td>
<td>32 M</td>
</tr>
<tr>
<td>2010</td>
<td>28 M</td>
<td>44 M</td>
</tr>
<tr>
<td>2011</td>
<td>37 M</td>
<td>64 M</td>
</tr>
<tr>
<td>2012</td>
<td>56 M</td>
<td>67 M</td>
</tr>
<tr>
<td>2013</td>
<td>80 M</td>
<td>88 M</td>
</tr>
<tr>
<td>2014</td>
<td>96 M</td>
<td>89 M</td>
</tr>
<tr>
<td>2015</td>
<td>112 M</td>
<td>114 M</td>
</tr>
<tr>
<td>2016</td>
<td>139 M</td>
<td>162 M</td>
</tr>
<tr>
<td>2017</td>
<td>194 M</td>
<td>213 M</td>
</tr>
<tr>
<td>2018</td>
<td>358 M</td>
<td>164 M</td>
</tr>
</tbody>
</table>

**CAGR² (2007-2018)**

- +71%
- +62%
- +119%

**Share of retail sales**
- 100%
- 98%
- 90%
- 88%
- 85%
- 88%
- 91%
- 84%
- 69%
- 65%
- 54%

**Share of hospital sales**
- 0%
- 2%
- 10%
- 12%
- 15%
- 12%
- 9%
- 16%
- 31%
- 35%
- 46%

**Note:** In 2016, 2017 and 2018, the net prices were respectively 50%, 55% and 52% lower than the ex-factory prices excluding taxes and rebates (mainly through tenders) on the hospital market. The rebates granted in the retail market are considered as negligible.

**Sources:** GERS – Smart Pharma Consulting analyses

¹ Net prices = Ex-factory prices excluding taxes and including rebates – ² Compound annual growth rate
In terms of therapeutic classes, anti-TNFs dominate the French biosimilars market, followed by monoclonal antibody antineoplastics and colony-stimulating factors.

**Distribution of the biosimilars market by therapeutic class (2013 – 2018)**

<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total market</td>
<td>85</td>
<td>95</td>
<td>132</td>
<td>212</td>
<td>304</td>
<td>538</td>
</tr>
<tr>
<td>Fractionated heparins</td>
<td>15</td>
<td>18</td>
<td>21</td>
<td>23</td>
<td>25</td>
<td>138</td>
</tr>
<tr>
<td>Gonadotrophins</td>
<td>28</td>
<td>33</td>
<td>61</td>
<td>67</td>
<td>47</td>
<td>9</td>
</tr>
<tr>
<td>Human insulins</td>
<td>2</td>
<td>1</td>
<td>6</td>
<td>11</td>
<td>6</td>
<td>137</td>
</tr>
<tr>
<td>Growth hormones</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>7</td>
<td>9</td>
<td>304</td>
</tr>
<tr>
<td>Erythropoiesis-stimulating agents</td>
<td>81</td>
<td>61</td>
<td>6</td>
<td>4</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Colony-stimulating factors</td>
<td>137</td>
<td>17</td>
<td>1</td>
<td>1</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Monoclonal antibody antineoplastics</td>
<td>198</td>
<td>138</td>
<td>137</td>
<td>304</td>
<td>538</td>
<td></td>
</tr>
<tr>
<td>Anti-TNFs</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**CAGR** 2013-2018: N/A

**2017-2018 growth:** +44.5%

**Market share 2013:** 0.0%

**2018:** 0.8%

Sources: GERS – Smart Pharma Consulting analyses


**Distribution of the biosimilars market by therapeutic class (2013 – 2018)**

**Total market**

- Anti-TNFs: 0 (2013), 0 (2014), 0 (2015), 0 (2016), 0 (2017), 0 (2018)
With 3 biologic originators whose patent has expired, 7 biosimilars launched by 5 pharma companies, anti-TNF biosimilars sales reached €198 M in 2018

Anti-TNF biosimilar drugs marketed in France (2018)

<table>
<thead>
<tr>
<th>INN¹ (Originator)</th>
<th>Product name</th>
<th>Pharma company</th>
<th>Launch date</th>
<th>Hospital sales²</th>
<th>Retail sales²</th>
<th>Total sales²</th>
<th>Biosimilars penetration³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infliximab (Remicade, MSD)</td>
<td>Inflectra</td>
<td>Pfizer</td>
<td>Feb. 2015</td>
<td>€95.8 M</td>
<td>€0.0 M</td>
<td>€95.8 M</td>
<td>69.6%</td>
</tr>
<tr>
<td></td>
<td>Remsima</td>
<td>Biogaran</td>
<td>Feb. 2015</td>
<td>€52.0 M</td>
<td>€0.0 M</td>
<td>€52.0 M</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Flixabi</td>
<td>Biogen</td>
<td>Mar. 2017</td>
<td>€27.6 M</td>
<td>€0.0 M</td>
<td>€27.6 M</td>
<td></td>
</tr>
<tr>
<td>3 products</td>
<td>3 companies</td>
<td></td>
<td></td>
<td>€175.5 M</td>
<td>€0.0 M</td>
<td>€175.5 M</td>
<td></td>
</tr>
<tr>
<td>Etanercept (Enbrel, Pfizer)</td>
<td>Benepali</td>
<td>Biogen</td>
<td>Oct. 2016</td>
<td>€0.1 M</td>
<td>€19.0 M</td>
<td>€19.1 M</td>
<td>20.3%</td>
</tr>
<tr>
<td></td>
<td>Erelzi</td>
<td>Sandoz</td>
<td>Nov. 2017</td>
<td>€0.0 M</td>
<td>€2.2 M</td>
<td>€2.2 M</td>
<td></td>
</tr>
<tr>
<td>2 products</td>
<td>2 companies</td>
<td></td>
<td></td>
<td>€0.1 M</td>
<td>€21.2 M</td>
<td>€21.3 M</td>
<td></td>
</tr>
<tr>
<td>Adalimumab (Humira, AbbVie)</td>
<td>Amgevita</td>
<td>Amgen</td>
<td>Oct. 2018</td>
<td>€0.0 M</td>
<td>€0.5 M</td>
<td>€0.5 M</td>
<td>2.3%</td>
</tr>
<tr>
<td></td>
<td>Imraldi</td>
<td>Biogen</td>
<td>Oct. 2018</td>
<td>€0.0 M</td>
<td>€0.3 M</td>
<td>€0.3 M</td>
<td></td>
</tr>
<tr>
<td>2 products</td>
<td>2 companies⁴</td>
<td></td>
<td></td>
<td>€0.0 M</td>
<td>€0.8 M</td>
<td>€0.8 M</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>7 products</td>
<td>5 companies</td>
<td></td>
<td>€175.6 M</td>
<td>€22.0 M</td>
<td>€197.6 M</td>
<td></td>
</tr>
</tbody>
</table>

Sources: GERS – Smart Pharma Consulting analyses

¹ International Non-propriety Name – ² Ex-factory prices excluding rebates and taxes – ³ Biosimilar penetration in volume in December 2018 – ⁴ As of June 2019, two more biosimilars have entered the market: Hulio (Mylan) and Hyrimoz (Sandoz). An additional biosimilar, Idacio (Fresenius Kabi) is expected in the coming months
With 2 biologic drugs from Roche whose patent has expired, 5 biosimilars launched by 4 companies, rituximab & trastuzumab biosimilars sales reached € 137 M in 2018

**Monoclonal antibody antineoplastics biosimilar drugs marketed in France (2018)**

<table>
<thead>
<tr>
<th>INN¹ (Originator)</th>
<th>Product name</th>
<th>Pharma company</th>
<th>Launch date</th>
<th>Hospital sales²</th>
<th>Retail sales²</th>
<th>Total sales²</th>
<th>Biosimilars penetration³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rituximab (MabThera, Roche)</td>
<td>Truxima</td>
<td>Biogaran</td>
<td>Sep. 2017</td>
<td>€ 104.8 M</td>
<td>€ 0.0 M</td>
<td>€ 104.8 M</td>
<td>82.2%</td>
</tr>
<tr>
<td></td>
<td>Rixathon</td>
<td>Sandoz</td>
<td>Jan. 2018</td>
<td>€ 18.1 M</td>
<td>€ 0.0 M</td>
<td>€ 18.1 M</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 products</td>
<td>2 companies</td>
<td></td>
<td>€ 122.8 M</td>
<td>€ 0.0 M</td>
<td>€ 122.8 M</td>
<td></td>
</tr>
<tr>
<td>Trastuzumab (Herceptin, Roche)</td>
<td>Herzuma</td>
<td>Biogaran</td>
<td>Jul. 2018</td>
<td>€ 10.7 M</td>
<td>€ 0.0 M</td>
<td>€ 10.7 M</td>
<td>62.3%</td>
</tr>
<tr>
<td></td>
<td>Ontruzant</td>
<td>MSD</td>
<td>Sep. 2018</td>
<td>€ 2.4 M</td>
<td>€ 0.0 M</td>
<td>€ 2.4 M</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Kanjinti</td>
<td>Amgen</td>
<td>Aug. 2018</td>
<td>€ 1.4 M</td>
<td>€ 0.0 M</td>
<td>€ 1.4 M</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 products</td>
<td>3 companies</td>
<td></td>
<td>€ 14.5 M</td>
<td>€ 0.0 M</td>
<td>€ 14.5 M</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>5 products</td>
<td>4 companies</td>
<td></td>
<td>€ 137.3 M</td>
<td>€ 0.0 M</td>
<td>€ 137.3 M</td>
<td></td>
</tr>
</tbody>
</table>

Sources: GERS – Smart Pharma Consulting analyses

¹ International Non-propriety Name – ² Ex-factory prices excluding rebates and taxes – ³ Biosimilar penetration in volume in December 2018
With 2 biologic drugs from Amgen whose patent has expired, 5 biosimilars launched by 5 pharma companies, G-CSF biosimilars sales reached €81 M in 2018

**Colony-stimulating factors biosimilar drugs marketed in France (2018)**

<table>
<thead>
<tr>
<th>INN¹ (Originator)</th>
<th>Product name</th>
<th>Pharma company</th>
<th>Launch date</th>
<th>Hospital sales²</th>
<th>Retail sales²</th>
<th>Total sales²</th>
<th>Biosimilars penetration³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filgrastim (Neupogen, Amgen)</td>
<td>Zarzio</td>
<td>Sandoz</td>
<td>Oct. 2009</td>
<td>€10.7 M</td>
<td>€36.4 M</td>
<td>€47.1 M</td>
<td>94.1%</td>
</tr>
<tr>
<td></td>
<td>Nivestim</td>
<td>Pfizer</td>
<td>Jun. 2011</td>
<td>€4.9 M</td>
<td>€18.6 M</td>
<td>€23.5 M</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tevagrastim</td>
<td>Teva</td>
<td>Mar. 2010</td>
<td>€1.5 M</td>
<td>€5.1 M</td>
<td>€6.7 M</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Accofil</td>
<td>Arrow</td>
<td>Feb. 2016</td>
<td>€2.6 M</td>
<td>€0.8 M</td>
<td>€3.3 M</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4 products</td>
<td>4 companies</td>
<td></td>
<td>€19.7 M</td>
<td>€60.9 M</td>
<td>€80.6 M</td>
<td></td>
</tr>
<tr>
<td>Pegfilgrastim (Neulasta, Amgen)</td>
<td>Pelgraz</td>
<td>Accord Healthcare</td>
<td>Nov. 2018</td>
<td>€0.0 M</td>
<td>€0.2 M</td>
<td>€0.2 M</td>
<td>2.5%</td>
</tr>
<tr>
<td></td>
<td>1 product</td>
<td>1 company</td>
<td></td>
<td>€0.0 M</td>
<td>€0.2 M</td>
<td>€0.2 M</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 product</td>
<td>1 company</td>
<td></td>
<td>€0.0 M</td>
<td>€0.2 M</td>
<td>€0.2 M</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>5 products</td>
<td>5 companies</td>
<td></td>
<td>€19.7 M</td>
<td>€61.1 M</td>
<td>€80.8 M</td>
<td></td>
</tr>
</tbody>
</table>

Sources: GERS – Smart Pharma Consulting analyses

¹ International Non-propriety Name – ² Ex-factory prices excluding rebates and taxes – ³ Biosimilar penetration in volume in December 2018
Epoetin and somatropin biosimilars, whose first products were launched ~10 years ago, reached penetration rates of almost 50% in December 2018

Other biosimilar drugs marketed in France (2018)

<table>
<thead>
<tr>
<th>EPhMRA 4 therapeutic class</th>
<th>INN(^1) (Originator)</th>
<th>Product name</th>
<th>Pharma company</th>
<th>Launch date</th>
<th>Hospital sales(^2)</th>
<th>Retail sales(^2)</th>
<th>Total sales(^2)</th>
<th>Biosimilars penetration(^3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythropoiesis-stimulating agents</td>
<td>Epoetin (Eprex, Janssen)</td>
<td>Binocrit</td>
<td>Sandoz</td>
<td>Jul. 2008</td>
<td>€ 7.1 M</td>
<td>€ 0.8 M</td>
<td>€ 29.3 M</td>
<td>€ 36.4 M</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Retacrit</td>
<td>Pfizer</td>
<td>Mar. 2009</td>
<td>€ 0.6 M</td>
<td>€ 16.5 M</td>
<td>€ 7.2 M</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eporatio(^4)</td>
<td>Teva</td>
<td>May 2010</td>
<td>€ 0.6 M</td>
<td>€ 6.6 M</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Growth hormones</td>
<td>Somatropin (Genotonorm, Pfizer)</td>
<td>Omnitrope</td>
<td>Sandoz</td>
<td>May 2007</td>
<td>€ 0.0 M</td>
<td>€ 25.4 M</td>
<td>€ 25.4 M</td>
<td>49.3%</td>
</tr>
<tr>
<td>Human insulins</td>
<td>Insulin glargine (Lantus, Sanofi)</td>
<td>Abasaglar</td>
<td>Lilly</td>
<td>Jan. 2016</td>
<td>€ 2.3 M</td>
<td>€ 15.5 M</td>
<td>€ 17.8 M</td>
<td>17.8%</td>
</tr>
<tr>
<td>Gonadotrophins</td>
<td>Follitropin alfa (Gonal-F, Merck)</td>
<td>Bemfola</td>
<td>Gedeon Richter</td>
<td>May 2015</td>
<td>€ 0.0 M</td>
<td>€ 10.0 M</td>
<td>€ 10.0 M</td>
<td>48.9%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ovaleap</td>
<td>Theramex</td>
<td>May 2016</td>
<td>€ 0.0 M</td>
<td>€ 3.2 M</td>
<td>€ 3.2 M</td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fractionated heparins</td>
<td>Enoxaparin sodium (Lovenox, Sanofi)</td>
<td>Enoxaparine</td>
<td>Biogaran</td>
<td>Sept. 2018</td>
<td>€ 0.1 M</td>
<td>€ 4.4 M</td>
<td>€ 4.5 M</td>
<td>8.0%</td>
</tr>
</tbody>
</table>

Sources: GERS – Smart Pharma Consulting analyses

\(^1\) International Non-propriety Name – \(^2\) Ex-factory prices excluding rebates and taxes – \(^3\) Biosimilar penetration in volume in December 2018 – \(^4\) Eporatio is not a biosimilar per se but rather a “me-too” product
Biosimilar penetration is faster and faster, notably in the hospital market where it ranged from ~62% (for trastuzumab) to ~82% (for rituximab) in December 2018.

Biosimilars market penetration (as a % sales in volume)

Sources: GERS – Smart Pharma Consulting analyses

1 Excluding the 1,400 mg subcutaneous form, that is not yet subject to biosimilars competition
2 Excluding the 600 mg subcutaneous form, that is not yet subject to biosimilars competition
3 Products bought and/or delivered at hospitals and retail pharmacies
4 Products exclusively bought and delivered at hospitals
Infliximab biosimilars penetration reached ~70% of the market in volume, ~4 years after biosimilar entry, despite MSD competitive price offering

**Penetration rate in volume – Infliximab case study**

Biosimilars penetration as a % of infliximab sales in standard units

<table>
<thead>
<tr>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Originator</td>
</tr>
<tr>
<td>Status</td>
</tr>
<tr>
<td>EPHMRA class</td>
</tr>
<tr>
<td>Indications</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sales dynamics (2014 – 2018)</th>
</tr>
</thead>
<tbody>
<tr>
<td>€M³</td>
</tr>
<tr>
<td>2014</td>
</tr>
<tr>
<td>2015</td>
</tr>
<tr>
<td>2016</td>
</tr>
<tr>
<td>2017</td>
</tr>
<tr>
<td>2018</td>
</tr>
</tbody>
</table>

**Sources:** GERS – Thériaque – Smart Pharma Consulting analyses

1 Acquired by Pfizer in September 2015 – ² Activity-based costing – ³ Ex-factory price, excluding VAT and rebates – ⁴ Compound annual growth rate
The French biosimilars market is split in two different segments that require, from pharma companies, different strategies, tactics and organizational models to succeed.

### The biosimilars market segments

<table>
<thead>
<tr>
<th>Hospital-only market segment</th>
<th>Hybrid market segment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td><strong>Definition</strong></td>
</tr>
<tr>
<td><strong>Pricing</strong></td>
<td><strong>Pricing</strong></td>
</tr>
<tr>
<td><strong>Purchasing</strong></td>
<td><strong>Purchasing</strong></td>
</tr>
<tr>
<td><strong>Medico-marketing activities</strong></td>
<td><strong>Medico-marketing activities</strong></td>
</tr>
<tr>
<td><strong>Market size &amp; profit level</strong></td>
<td><strong>Market size &amp; profit level</strong></td>
</tr>
</tbody>
</table>

**Hospital-only market segment**
- Prescribed, purchased and delivered at hospitals (e.g. infliximab, rituximab, trastuzumab)
- Free pricing for drugs included in T2A system\(^1\)
- Responsibility tariff set by the CEPS\(^2\) for drugs on-top of the T2A list\(^3\) (e.g. infliximab, rituximab)
- Mainly purchased through tenders and/or to a lower extent through negotiated agreements
- Possibility to grant rebates to hospitals
- Strong price pressure
- Medical activity carried out by MSLs to reassure prescribers about the quality of the biosimilars
- Key account management activity carried out by KAMs to win tenders and set up a follow up plan
- Market size 2018: € 164 M (net price)
- Leading players profitability: medium to high

**Hybrid market segment**
- Prescribed by hospital and/or office-based specialists, purchased and delivered by hospital and retail pharmacies (e.g. epoetin, filgrastim) or retail pharmacies only (e.g. follitropin alfa, somatropin)
- Ex-factory price set by the CEPS initially at -30% or -40% below the original biologic on the hospital and the retail market segments, respectively
- The level of rebates to retail pharmacies is limited to a maximum of 2.5% of the ex-factory price which is in general granted by wholesalers\(^4\)
- Limited price pressure on retail sales
- Medical activity carried out by MSLs to reassure prescribers about the quality of the biosimilars
- Promotional activity carried out by marketers and medical reps to be prescribed to in- and out-patients
- Market size 2018: € 194 M (net price = price list)
- Leading players profitability: high

---

\(^1\) Activity-based costing system similar to a diagnosis-related group-based funding system
\(^2\) Drug pricing committee
\(^3\) Includes the most expensive drugs for which the CEPS sets a maximum reimbursed price called “Responsibility tariff” which is 30% (for hospital-only drugs) below the price of the original biologic before its price is cut, following biosimilars entry
\(^4\) Pharma companies are not used to giving discounts to retail pharmacists for their biosimilars

Sources: Smart Pharma Consulting analyses
Substitution of biosimilars by retail pharmacists, at treatment initiation, is legal since 2013, but the absence of the corresponding decree does not allow its implementation.

### Regulations specific to biosimilars

#### Biosimilar drugs

- A biosimilar drug is any biological drug that has the same qualitative and quantitative composition of active substance and the same pharmaceutical form as a biological originator…

- … but does not fulfill the conditions for being regarded as a generic due to differences related in particular to raw material variability or manufacturing processes requiring the achievement of additional preclinical and clinical data under regulatory conditions…

- … demonstrating that the biosimilar:
  - Is similar to the biological originator
  - Does not differ significantly from the biological originator in terms of quality, efficacy and safety

#### Biosimilar register

- The ANSM\(^2\) has created in 2017 similar biologic groups, each of them defined by a reference biologic and its corresponding biosimilars, listed by brand name

#### Biosimilar substitution right

- France was the first European country to allow the substitution of biosimilars, in December 2013

- Biosimilars substitution is only permitted if:
  - A new treatment is started
  - Within the same similar biologic group
  - The prescriber has not explicitly prohibited, in writing, the substitution of the prescribed drug
  - The pharmacist has informed the prescriber…
  - … and recorded the details of biosimilar dispensed

- In the absence of a decree defining the conditions of substitution, the law has not yet been implemented

#### Inter-changeability

- The ANSM has specified in May 2016 that inter-changeability was possible between biologic drugs belonging to the same similar biologic group

---


1 A specific legal framework for biosimilar medicines was introduced in Europe on March 31\(^{st}\), 2004 and the first biosimilar was authorized by the European Commission in April 2006 – 2 “Agence nationale de sécurité du médicament”: National Agency for the Safety of Medicines and Health Products
The health authorities are strongly determined to accelerate the penetration of biosimilars, but remain relatively cautious to avoid any potential public health issue

### Health authorities measures to boost biosimilars

#### LFSS 2018 – Focus on the CAQES
- Since January 2018, contracts between hospitals, health regional agencies and health insurance named CAQES, have set prescription targets for biosimilars

  **Objective**
  - Achieve 70% penetration of hospital biosimilars in units, at national level²

  **Implementation**
  - Promotion of biosimilars prescriptions in the reference list
  - Remuneration of hospitals: 20% of the price difference between reference and biosimilar products

#### 2017 – Ministerial Order
- The DGOS³, DSS⁴, DGS⁵ and the UNCAM⁶ published an order on October 12th, 2017 to require the Regional Health Agencies (ARS) to promote the use of biosimilar drugs

  - As a result, ARS are invited to promote the use of biosimilars by:
    - Informing patients
    - Harmonizing prescribers practices in favor of biosimilars
    - Helping hospitals organize tenders as soon as biosimilars are on the market
    - Developing financial tools to measure the savings related to biosimilars

  - The DGOS has informed that physicians are authorized to switch one biological drug by another similar one during a treatment

#### LFSS 2018 – Article 51
- In August 2018, the Ministry of Health launched an experiment with 45 selected hospitals to stimulate their prescription of biosimilars delivered in retail pharmacies

  **Objective**
  - 15-points increase in biosimilar prescription rates vs. non-experimental hospitals

  **Implementation**
  - Duration: 3 years
  - Scope: etanercept and insulin glargine at national level⁷
  - Remuneration of hospital services: 30% of the price difference between reference and biosimilar products

---

**Sources:**

- Decree related to CAQES and setting quality and efficiency reference objectives – Smart Pharma Consulting analyses
- LFSS 2018: contract for healthcare quality and efficiency enhancement
- In December 2017, the government has set the global (hospital and retail markets) objective of 80% biosimilar penetration by 2022
- Directorate of Health Care Supply
- Directorate of Social Security
- Directorate General for Health
- National Union of Health Insurance Funds
- Adalimumab has entered in the scope of the experiment in the second quarter 2019
Exempted for trastuzumab and etanercept, whose first biosimilars were launched in 2018 and 2016 respectively, the CEPS dropped all reference prices by ~40%.

### Historical imposed price cuts over time

#### Infliximab (Remicade)

<table>
<thead>
<tr>
<th>Hospital-only products</th>
<th>Initial price</th>
<th>Nov. 2014</th>
<th>Sept. 2016</th>
<th>Marc. 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infliximab 100 mg unit price¹</td>
<td>100% €482</td>
<td>90% €434</td>
<td>79% €382</td>
<td>60% €291</td>
</tr>
<tr>
<td><strong>Biosimilars entry</strong> (Feb. 2015)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Rituximab (MabThera)

<table>
<thead>
<tr>
<th>Hospital-only products</th>
<th>Initial price</th>
<th>Jan. 2017</th>
<th>Jan. 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rituximab 500 mg unit price¹</td>
<td>100% €1,318</td>
<td>90% €1,187</td>
<td>63% €831</td>
</tr>
<tr>
<td><strong>Biosimilars entry</strong> (Sep. 2017)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Trastuzumab (Herceptin)

<table>
<thead>
<tr>
<th>Hospital-only products</th>
<th>Initial price</th>
<th>Apr. 2016</th>
<th>Jan. 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trastuzumab 600 mg unit price¹</td>
<td>100% €1,476</td>
<td>93% €1,373</td>
<td>88% €1,304</td>
</tr>
<tr>
<td><strong>Biosimilars entry</strong> (Jul. 2018)</td>
<td></td>
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</tbody>
</table>

#### Filgrastim (Neupogen)

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Filgrastim 30 MU (0.6 mg/ml) unit price²</td>
<td>100% €96</td>
<td>85% €82</td>
<td>72% €69</td>
<td>61% €59</td>
</tr>
<tr>
<td><strong>Biosimilars entry</strong> (Oct. 2009)</td>
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</tbody>
</table>

#### Epoetin (Eprex)

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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Epoetin 40,000 UI/ml unit price²</td>
<td>100% €328</td>
<td>97% €318</td>
<td>97% €286</td>
<td>81% €266</td>
<td>73% €239</td>
<td>63% €206</td>
</tr>
<tr>
<td><strong>Biosimilars entry</strong> (Jul. 2008)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Etanercept (Enbrel)

<table>
<thead>
<tr>
<th>Hybrid products²</th>
<th>Initial price</th>
<th>Sep. 2016</th>
<th>Jan. 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Etanercept 50 mg unit price²</td>
<td>100% €719</td>
<td>97% €697</td>
<td>90% €646</td>
</tr>
<tr>
<td><strong>Biosimilars entry</strong> (Oct. 2016)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sources: French National Health Insurance prices database – Smart Pharma Consulting analyses

¹ Ex-factory price per standard unit, excluding rebates and taxes
² Products with sales at hospital levels and retail pharmacies
Biosimilars prices on the hospital market are either free or set by the drug pricing committee (CEPS), while on the ambulatory market they are always regulated.

### Biosimilars price regulation – New Health Authorities Doctrine

#### Hospital market segment

- If the reference biological drug is **included in the T2A** (activity-based costing system), thus its price, as well as its corresponding biosimilars ones, will be **unregulated**
- If the reference biological drug is on:
  - The top of T2A hospital drug list\(^1\) or
  - The reassigned drug list\(^2\)
the CEPS (drug pricing committee) applies the following pricing principles, when the first biosimilar enters the market:
  - A 30% price cut for the originator and its biosimilars
  - 24 months and 48 months later, 10% to 30% additional price cuts depending on difference observed between actual net prices and prices set by the CEPS

#### Ambulatory market segment

**At the entry date of biosimilars:**
- The CEPS sets the price of biosimilars **40% below** the price of the originator
- The originator is imposed a price cut of **20%**

**24 months and 42 months after the entry of the first biosimilar:**
- Additional price cuts aimed at **price convergence**...
- … and depending on the respective **market shares** of the originator and of its biosimilars will be imposed

---

Sources: CEPS Activity Reports – LEEM – IRDES – Decree of March 25\(^{th}\), 2016 regarding modalities of inscription to the on top of T2A list – Smart Pharma Consulting analyses

\(^1\)This list includes expensive products which are funded on top of the hospital service tariffs (hospital budget) to improve patients access to innovation – \(^2\)These products, which are on the retrocession list, can be sold to outpatients by the hospital pharmacies and, in such a case, are funded by the National Health Insurance Fund.
Cost containment policies tend to make hospital prescribers increasingly concerned about costs induced by their prescriptions, providing opportunities for biosimilars

<table>
<thead>
<tr>
<th>Drugs dispensed at hospitals</th>
<th>Drugs dispensed at retail pharmacies</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Since 2007, hospital expenditures are covered by the National Health Insurance Fund according to their activity level, based on a fixed fee-for-service model, called T2A¹</td>
<td>▪ The article 47 of the Social Security Act for 2010 introduced a new measure to contain the cost of drugs dispensed in retail pharmacies, but prescribed at hospitals, as this cost was increasing much faster than that related to primary care prescriptions</td>
</tr>
<tr>
<td>▪ As a result, hospitals have a strong incentive to pay the lowest price, as possible, for drugs and for the other goods they purchase, to achieve a balanced budget</td>
<td>▪ This measure sets an annual maximum growth rate (+4.0% for 2018 and +3.3% for 2019) of drug expenditure related to hospital prescriptions that are bought at retail pharmacies by patients</td>
</tr>
<tr>
<td>▪ For drugs on “the top of T2A” and/or on the reassigned list, hospitals are reimbursed by the National Health Insurance Fund, at the reference price set by the CEPS²</td>
<td>▪ If exceeded, the ARS⁴ may place the offending hospital under its supervision to compel it to improve prescribing practices, and may possibly demand financial penalties</td>
</tr>
<tr>
<td>▪ However, hospitals may obtain a lower price and, in such a case, the saving will be equitably distributed between hospitals and the National Health Insurance Fund</td>
<td></td>
</tr>
</tbody>
</table>

Biosimilars may contribute to reduce hospitals costs, but in a relatively limited proportion, knowing that drugs account for ~6% of total hospital budget³

Prescription of biosimilars may help better control the cost evolution of drugs prescribed in hospital and dispensed in retail pharmacies


¹ Tarification à l’activité – ² Drug pricing committee – ³ Salaries account for ~70%, general & administrative expenses for ~18% and medical devices for ~6% – ⁴ Regional health agency
2.5 years after biosimilars entry, the net price of infliximab (ex-factory price minus hospital rebates) has been reduced by ~76%

Hospital pricing evolution – Infliximab case study

Reference prices applied to infliximab

- Initial reference price for Remicade: 100% (€482.67)*
- 1st reference price cut by the CEPS Nov. 2014: 90% (€434.40)*
- 2nd reference price cut by the CEPS Sept. 2016: 79% (€382.28)*
- 3rd reference price cut by the CEPS Mar. 2018: 60% (€290.53)*

Paris Hospital Group (AP-HP) tenders

- 1st tender won by Inflectra (Hospira) July 2015: 49% (€238.92)*
- 1st tender won by Flixabi (Biogen) Aug. 2017: 24% (€114.68)*

Sources: Desk research – APM News – Interviews – Smart Pharma Consulting analyses

1 Applied to all infliximab brands, including biosimilars
The main criteria that will determine biosimilars listing in hospitals are product characteristics and economic aspects according to this pilot study.

Listing procedures and protocols in hospitals

Criteria driving preference to list drugs subject to biosimilars competition at hospitals

- **Product characteristics**
  - 39%
  - "The methods of conservation of the products are important. For example, products which do not need the respect of the cold chain are favoured" (2)
  - "The ease of use and the safety of injection of the device is important" (1)
  - "The bioequivalence studies are essential to adopt a biosimilar" (1)

- **Economic aspects**
  - 38%
  - "Are to be considered even when the volumes of drugs in hospitals remain low such as for G-CSF" (2)
  - "Important criterion given the current context of willingness to control health expenditure" (2)
  - "One of the most important criteria for biosimilars" (2)

- **Corporate reputation**
  - 10%
  - "We have more confidence in the most reputable pharmaceutical companies because we know the quality of their products and their ability to meet their commitments in terms of delivery times" (2)

- **Logistics aspects**
  - 8%
  - "Could be of interest (e.g. support during the implementation of treatments, help in organizing the services of hospitals)" (2)

- **Other services**
  - 6%

Source: Interviews with 4 hospital pharmacists (October 2018) – Smart Pharma Consulting analyses

(X): Number of quotes
HCPs would adopt biosimilars provided their bioequivalence to the originator is proven and their pricing generates savings

Expectations from HCPs for biosimilars

“What factors might convince you to prescribe a biosimilar once the molecule has fallen into the public domain?”

- “A drop in pricing” (10)
- “Bioequivalence to the original brand” (2)
- “An optimal presentation of the product: no reconstitution, already packaged in the syringe!” (1)
- “That the treatment is in adequacy with the challenges and prescription goals of the CAQES¹ plan” (1)
- “That the treatment be listed within the Unicancer² market” (1)

“What would be the barriers to use a biosimilar?”

- “If there is an uncertainty about the true biosimilarity of the product due to fewer clinical studies and a lack of perspective on its use” (4)
- “If it is not listed within my hospital” (3)
- “If the packaging is less convenient to use” (2)

“What would you recommend pharma companies to do to reinforce your preference?”

- “To offer competitive prices where the savings made by the healthcare facility are substantial” (4)
- “To perform clinical bioequivalence trials for biosimilar products with follow-up over time, and injection site tolerance tests” (2)
- “To provide field monitoring services to ensure proper use of products” (2)
- “To develop long-acting forms and to target product conservation issues” (2)
- “To stop focusing on medico-economics only and to invest in clinical studies too” (1)

Number of respondents: 10

Source: Interviews with 6 hospital physicians and 4 hospital pharmacists (October 2018) – Smart Pharma Consulting analyses

¹ Contract for the improvement of quality and efficiency of care – ² Hospital network regrouping the 18 regional centers for the fight against cancer (CRLCC) entirely dedicated to oncology and including a national purchasing unit
In 2018, Biogaran, Pfizer and Sandoz generated individually more than €100M sales and represented together ~82% of the French biosimilars market in value terms.

### Top 10 companies on the biosimilars market – In value\(^1\) (2018)

![Bar chart showing the top 10 companies on the biosimilars market in value terms in 2018.]

- **Biogaran**: €172M
- **Pfizer**: €137M
- **Sandoz**: €129M
- **Biogen**: €47M
- **Lilly**: €18M
- **Teva**: €17M
- **Gedeon Richter**: €10M
- **Actavis / Arrow**: €3M
- **MSD**: €2M
- **Amgen**: €2M

**Average turnover = €54M**

**Market share**

- **Biogaran**: 32.0%
- **Pfizer**: 25.4%
- **Sandoz**: 24.1%
- **Biogen**: 8.7%
- **Lilly**: 3.3%
- **Teva**: 3.2%
- **Gedeon Richter**: 1.9%
- **Actavis / Arrow**: 0.6%
- **MSD**: 0.4%
- **Amgen**: 0.4%

**Biosimilars weight in the portfolio**

- **Biogaran**: 14.2%
- **Pfizer**: 10.0%
- **Sandoz**: 19.2%
- **Biogen**: 12.3%
- **Lilly**: 5.0%
- **Teva**: 2.5%
- **Gedeon Richter**: 66.9%
- **Actavis / Arrow**: 0.7%
- **MSD**: 0.2%
- **Amgen**: 0.3%

**2017-2018 evolution**

- **Biogaran**: +277.5%
- **Pfizer**: +7.2%
- **Sandoz**: +46.4%
- **Biogen**: +277.4%
- **Lilly**: +161.9%
- **Teva**: +11.3%
- **Gedeon Richter**: +38.6%
- **Actavis / Arrow**: +311.4%
- **MSD**: N/A
- **Amgen**: N/A

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**Sources:** GERS – Smart Pharma Consulting analyses

\(^1\) Both retail and hospital sales – \(^2\) Ex-factory price, excluding taxes and rebates – \(^3\) Part of Aurobindo, since its acquisition of Actavis in 2014
In 2018, the top 4 companies operating on the French biosimilars market had from 2 to 5 brands, and sales split on the hospital and retail market segments.

**Top 4 companies on the biosimilars market – Portfolio structure (2018)**

<table>
<thead>
<tr>
<th>Company</th>
<th>Brand</th>
<th>Market Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biogaran</td>
<td>Truxima</td>
<td>61%</td>
</tr>
<tr>
<td></td>
<td>Remsima</td>
<td>30%</td>
</tr>
<tr>
<td></td>
<td>Herzuma</td>
<td>30%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>~97% hospital-only drugs (i.e. Truxima, Remsima and Herzuma) prescribed and dispensed at hospital</td>
</tr>
</tbody>
</table>

| Pfizer   | Inflectra | 70%         |
|          | Nivestim  | 17%         |
|          | Retacrit  | 13%         |
|          |          | 26% retail pharmacies |

| Sandoz   | Benepali  | 41%         |
|          | Flixabi   | 59%         |
|          | Erelzi    | 2%          |
|          | Remsima   | 30%         |
|          | Zarzio    | 36%         |
|          | Nivestim  | 72%         |
|          |          | ~72% retail pharmacies |

| Biogen   | Benepali  | 41%         |
|          | Flixabi   | 59%         |
|          | Erelzi    | 2%          |
|          | Inflectra | 28%         |
|          | Nivestim  | 17%         |
|          | Retacrit  | 13%         |
|          | Remsima   | 30%         |
|          | Zarzio    | 36%         |
|          |          | ~40% retail pharmacies |

Sources: GERS – Smart Pharma Consulting analyses

1 Both retail and hospital sales, in ex-factory price, excluding taxes and rebates
2 Enoxaparin sodium
3 Trastuzumab
4 Infliximab
5 Rituximab
6 Epoetin
7 Filgrastim
8 Etanercept
9 Somatropin
The hospital-only biosimilar model appears to be less profitable than the hybrid one due to a much higher level of rebates granted by pharma companies.

### Estimated profitability of leading pharma companies on the biosimilars market (2018)

<table>
<thead>
<tr>
<th>Model</th>
<th>% of total sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td>100%</td>
</tr>
<tr>
<td>COGS¹ (excluding G&amp;A)</td>
<td>0%</td>
</tr>
<tr>
<td>Rebates to hospitals</td>
<td>0%</td>
</tr>
<tr>
<td>Medico-Marketing &amp; Sales</td>
<td>0%</td>
</tr>
<tr>
<td>G&amp;A</td>
<td>0%</td>
</tr>
<tr>
<td>EBITDA²</td>
<td>0%</td>
</tr>
</tbody>
</table>

#### Hospital-only biosimilar model

- Estimates based on annual sales of €~150 M generated by hospital-only biosimilars, with an average price list of 30% below the price of original brands before they enter the market.
- Average discounts to hospitals: -50% on price list (ex-factory price).
- Medico-marketing and sales costs, incl.: 5 KAMs and 5 MSLs.
- All other costs included in G&A.

#### Hybrid biosimilar model

- Estimates based on total annual sales of €~130 M of which €~90 M (72%) sold on the retail market, with an average price list of 40% below the price of original brands before they enter the market.
- Average discounts to hospitals: -50% to -90% on price list.
- Medico-marketing and sales costs, incl.: 3 KAMs, 40 Reps and 4 MSLs.
- All other costs included in G&A.

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Sources: Smart Pharma Consulting interviews with 5 General Managers of companies operating in the biosimilars market – Smart Pharma Consulting estimates

1. Cost of goods sold, including licensing fees and distribution costs
2. Earnings before interest, taxes, depreciation and amortization
3. Registration costs, head office costs, management costs, support functions
4. ~50% to hospital-only drugs, ~90% to non-hospital-only drugs. No significant rebates granted to retail pharmacies.
The most important success factor on the biosimilars market is to be the 1st market entrant and have the opportunity to remain the only biosimilar, for several months

Key success factors on the biosimilars market

**#1 – Be the 1st entrant**
- The historical analysis of the French market shows that the first entrants have a bigger market share than the followers (see p. 7 to 10)
- When a biosimilar benefits from a temporary period of monopoly, the probability it wins hospital tenders vs. the originator is very high
- Once a market has been won, it is locked for two to three years and the following biosimilars have to wait

**#2 – Offer the best price**
- The lowest the price offer, the highest the probability to win the tenders, especially for hospital-only products for which the savings for the hospital can be important, unlike for the biosimilars which are mainly bought at retail pharmacies
- Superior product attributes and/or services may help a biosimilar win a tender, in certain cases, only if its price offer is not superior to 5% to 10% than the lowest bidder

**#3 – Propose a better product**
- There are possibilities to differentiate biosimilars amongst themselves and vs. the corresponding original biologic:
  - Amgevita (Amgen) and Hulio (Mylan) propose a citrate-free version of adalimumab, as Humira (AbbVie) does since 2018, associated with less injection site-related pain\(^1\)
  - Benepali (Biogen), a biosimilar of etanercept, has shown in a European study\(^2\) that its autoinjector was easier to operate and more intuitive to use compared with the Enbrel (Pfizer) one, according to 86% of the 149 nurses who had been interviewed

**#4 – Develop services**
- Services proposed to hospital pharmacists, physicians, nurses and patients to facilitate the procurement, the prescription, the patient education and the drug usage may play a significant role to get preferred by hospital HCPs\(^3\)
- The market insight (knowledge and understanding) of in-field collaborators is a prerequisite to deliver highly valued services
- The quality of services will reinforce the reputation of the biosimilars company and preference of HCPs for its products

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\(^1\) Which is not the case for Imraldi (Biogen) and Hyrimoz (Sandoz) – \(^2\) Peter Nash, Rheumatol Ther (2016) 3:257-270 – \(^3\) Kunal Thaku, Rheumatol Ther (2016) 3:77-89 – \(^4\) Especially for products that are used in home care (e.g. subcutaneous anti-TNFs). It is essential at the launch phase to put in place observational studies in the key centers to boost the adoption of the biosimilar brand by the HCPs

Sources: Smart Pharma Consulting interviews with 5 General Managers of companies operating in the biosimilars market – Smart Pharma Consulting analyses
The biosimilars market should reach € 1.4 B in net value in 2023, with 1/3 of the growth driven by new biosimilars and 2/3 by increasing penetration of existing ones.

**Drugs sales forecast by segment (2013 – 2018 – 2023) – Net price**

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Market (Net price)</th>
<th>Hospital sales</th>
<th>Non reimbursed</th>
<th>Biosimilars (hospital &amp; retail)</th>
<th>Generics</th>
<th>Genericized originators</th>
<th>Patent-protected and other specific drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>€ 23,4 B</td>
<td>€ 5,5 B</td>
<td>€ 1,2 B</td>
<td>€ 0,1 B</td>
<td>€ 1,6 B</td>
<td>€ 1,3 B</td>
<td>€ 13,3 B</td>
</tr>
<tr>
<td>2018</td>
<td>€ 25,2 B</td>
<td>€ 7,0 B</td>
<td>€ 1,2 B</td>
<td>€ 1,8 B</td>
<td>€ 1,6 B</td>
<td>€ 1,8 B</td>
<td>€ 13,3 B</td>
</tr>
<tr>
<td>2023</td>
<td>€ 26,8 B</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>€ 13,2 B</td>
</tr>
</tbody>
</table>

**CAGR**

- **2013-2018**: +1.5%
- **2018-2023**: +1.2%

**Note:** In 2023, the biosimilars sold on the retail market should account for 68% of the total vs. 54% in 2018. The growth will be driven by new biosimilars* for 1/3 and by increasing penetration of existing ones for 2/3.

* Such as: teriparatide, secukinumab, eculizumab, belimumab, certolizumab, ipilimumab, bevacizumab, ranibizumab, liraglutide, cetuximab, natalizumab, abatacept, insulin lispro.

**Sources:** GERS dashboards – Smart Pharma Consulting estimates

1. Constant ex-factory prices including estimated rebates to hospital and retail pharmacists.
2. Excluding hospital sales of biosimilars but including all other products on the hospital budget and products invoiced in addition of the hospitalization charges (on top of T2A) and reassigned medicine sales.
4. Sales of drugs whose patents have not expired and of other specific products (calcium, sodium, potassium, paracetamol, etc.).
5. Compound annual growth rate.
The future growth of biosimilars will be mainly driven by health authorities measures introduced to boost HCPs\(^1\) prescriptions and by LOE\(^2\) of several high sales biologics

**Drivers & limiters of the biosimilars market (2013 – 2018 – 2023)**

<table>
<thead>
<tr>
<th>Drivers</th>
<th>Limiters</th>
</tr>
</thead>
</table>
| ▪ Biosimilars can increase access to treatments by:  
  – **Decreasing the overall treatment costs** and thus  
  – **Increasing affordability** (treatment of larger populations)  
  ▪ Increasing body of evidence showing the reliability, efficacy and quality of biosimilars | ▪ "Precaution principle": high cautiousness due to major public health issues in the past (e.g. blood transfusions contaminated with HIV, growth hormone case, sudden increase of pure red cell aplasia (PRCA) with Eprex\(^3\))  
  ▪ Substitution permitted by law since Dec. 2013 **but not implemented**, in the absence of the corresponding decree |
| ▪ They contribute to improve **hospitals financial balance**  
  ▪ Objective of penetration set at hospital level (CAQES)  
  ▪ **Financial incentives** proposed by health authorities for prescribing biosimilars (i.e. insulin glargine, etanercept, adalimumab) through the “article 51” experiment  
  ▪ For physicians, biosimilars are an **alternative to reference products** (in case of shortage for instance) | ▪ **No** guarantee of **perfect equivalence** with the reference product  
  ▪ Physicians generally have **close relationships** for many years with **original brand companies**, which may discourage them to use (extensively) biosimilars |
| ▪ None, except in cases where patients might have to bear (totally or partially) the cost of biological drugs | ▪ Preference for originators, on principle, especially in the case of serious and/or chronical diseases |
| ▪ **Increasing number of biosimilar** products per molecule accelerates market **penetration** and reduces hospital prices  
  ▪ ~13 **biologics** with high sales levels will lose their market exclusivity and face biosimilar competition by the end of 2023 | ▪ **The intensification of** competition drives biosimilar **prices down** and jeopardizes biosimilar companies **profitability**…  
  ▪ … rendering the **market** much less attractive for new players |

Sources: IQVIA PharmaStat (as of February 2019) – Smart Pharma Consulting analyses based on external interviews

\(^1\) Healthcare professionals  
\(^2\) Loss of exclusivity  
\(^3\) Increase in PRCA explained by an increase in the immunogenicity of Eprex following a formulation change in 1998, in which the human serum albumin stabilizer was replaced with polysorbate 80 and glycine
The market of biosimilars will benefit from the launch of new products in existing classes and in new classes by 2023

1. The market structure and dynamics
   - Since 2014, the market has increased four-fold\(^1\)
   - The penetration of hospital-only biosimilars is must higher than the one of biosimilars which are also delivered on the retail market

2. The French regulatory environment
   - Since 2017, health authorities have multiplied the initiatives to boost the biosimilars market
   - They have also developed a doctrine defining the decrease of biosimilars price over time

3. The customers behaviors
   - Hospital listing and prescribing depend mainly on product attributes and price
   - The absence of authorization for retail pharmacists to substitute biosimilars\(^2\) makes physicians the main driver

4. The competitive landscape
   - The top 3 leading players\(^3\) have generated more than €100 M gross sales in 2018, accounting for ~82% of the market in value
   - They have generated EBITDA\(^4\) rates ranging from 30% to 60% of gross sales

5. The key success factors
   - Enter first the market
   - Be the lowest-priced bidder…
   - … and/or offer superior services
   - Offer a better product than competitors

6. The 2018 – 2023 market growth
   - The market should increase by €1 B, thanks to the LOE of blockbusters (e.g. Avastin, Lucentis) and the increasing market penetration of recent biosimilars (e.g. Humira, Herceptin)

Sources: Smart Pharma Consulting analyses

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\(^1\) In net value – \(^2\) The implementation decree which is required to apply the law voted in December 2013 is still pending. No change is expected in the short term. The health authorities are not in favor of substitution at retail level for public health security and responsibility reasons – \(^3\) Biogaran, Pfizer and Sandoz – \(^4\) Earning before interest, taxes, depreciation and amortization
Smart Pharma Consulting has published several analytical reports and carried out consulting projects on biosimilars market attractiveness and key success factors.

**Selected publications & consulting projects on biosimilars**

### Examples of recent consulting projects

- **2019** Training of a biosimilar sales forces on the healthcare system at national, regional and local levels
- **2018** Assessment of the market potential for a biosimilar version of pegfilgrastim
- **2018** Assessment of the market potential for a biosimilar version of adalimumab
- **2018** Analysis and forecasting of the original and biosimilar versions of infliximab
- **2017** Assessment of the French biosimilars market potential for a leading generics player
- **2017** Development of an economic simulation tool for hospital KAM managers of a biosimilar company
- **2017** Set up of coordinated action plans for in-field collaborators of a company marketing biosimilars
- **2017** Training of hospital sales forces of a biosimilar company
- **2017** Assessment of potential sales for biosimilar versions of teriparatide and pegfilgrastim for a European mid-size pharma company

Sources: Smart Pharma Consulting
Hospital & Institutional Relationships in Regions

Benchmarking study carried out in France

Best-in-Class Series #9

Recommendations for Pharma Companies

January 2019

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E-mail: jmpeny@smart-pharma.com – Website: www.smart-pharma.com
The evolution of the healthcare environment in regions should spur pharma companies to adjust hospital KAMs\(^1\) and regional KIMs\(^2\) roles and responsibilities

**Scope & Objective of the study**

- The purpose of this position paper is to **analyze** the hospital KAMs (Key Account Managers) and the regional KIMs (Key Institution Managers) **roles and responsibilities** and to discuss the way they must adapt to the **evolution** of the regional healthcare environment in France.

- For so doing, Smart Pharma Consulting has:
  - **Reviewed** its previous **publications** on this topic
  - **Interviewed** senior executives from French affiliates of **7 pharma companies** (Biogen, Janssen, MSD, Pfizer, Roche, Novartis and Novo Nordisk) in July and November 2018.

- Based on these information, Smart Pharma Consulting **proposes**:
  - **Strategic** and
  - **Organizational recommendations**

regarding hospital KAMs and regional KIMs.

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\(^1\) Hospital KAMs are different from retail KAMs who are responsible to negotiate with purchasing groups / VTOs (Voluntary Trade Organizations) of retails pharmacies -- \(^2\) KIMs are responsible for Public Affairs at regional or local level.

**Sources:** Smart Pharma Consulting
The pharma market is increasingly driven by multiple stakeholders influencing physicians prescriptions and by secondary care drugs mainly prescribed at hospital.

**Evolution of the pharma market (1/2)**

**Therapeutic decision-making process evolution**

Health authorities → Physicians → Districts

Health insurers → Physicians → Districts

Nurses → Physicians → Districts

Patients → Physicians → Districts

PAGs → Physicians → Districts

**Global pharmaceutical market growth by segment (2017 – 2023)**

<table>
<thead>
<tr>
<th>Segment</th>
<th>2017 (Sales in USD B)</th>
<th>2023 (Sales in USD B)</th>
<th>CAGR 2017-2023</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary care</td>
<td>813 (70%)</td>
<td>1,011 (65%)</td>
<td>+4%</td>
</tr>
<tr>
<td>Secondary care</td>
<td>348 (30%)</td>
<td>545 (35%)</td>
<td>+8%</td>
</tr>
<tr>
<td>Sales in USD B</td>
<td>1,161</td>
<td>1,556</td>
<td>+5%</td>
</tr>
</tbody>
</table>

**Key principles**

1. **Patient Advocacy Groups**
2. Secondary care products which are mainly prescribed\(^1\) in hospital centers should grow faster than primary care products mainly initiated and prescribed by office-based physicians.

---

**Sources:** IQVIA Institute (March 2018) – Global OTC Drugs Market, Mordor Intelligence (May 2018) – Smart Pharma Consulting estimates

\(^1\) Patient Advocacy Groups – \(^2\) Secondary care products could also be initiated by hospital physicians and then renewed by office-based physicians, either specialists or GPs, depending on the treatment. In this case, the prescribing decision made by hospital physicians has a major impact on product sales.
Pharma companies must adopt an efficient organization to deal with bigger accounts, more and more price-sensitive, in which decision-making processes are complexified.

**Evolution of the pharma market (2/2)**

- The grouping of hospital centers has led pharma companies to deal with bigger accounts benefiting from a stronger bargaining power...
- ... in a context of economic pressure, making customers more price-sensitive than ever

**Pharma companies must address two key issues:**
- Protect, as much as possible, the price of their drugs
- Move from a B-to-C to a B-to-B business model in which the prescribing decision is made by multiple stakeholders having different views and objectives

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**Hospital market segment**

- Hospital center
  - Managing director
  - Financial director
  - Unit heads
  - Pharmacists
  - Nurses
  - Physicians

**Multiple internal influencers & decision-makers**

**Multiple external decision-makers** (ARS¹, OMEDIT², CPAM³, DRSM⁴, URPS⁵, PAGs⁶, etc.)

**Pharmaceutical companies**

- Customer-facing collaborators
  - MSL⁷
  - KAM⁸
  - Med reps
  - 1st line manager
  - KIM⁹

- Head office collaborators
  - Sales manager
  - Marketing manager
  - Product manager
  - CRA¹⁰
  - Medical manager

---

Sources: Smart Pharma Consulting

¹ Regional Health Agency – ² Observatory of Drugs, Medical Devices and Innovation – ³ Primary Fund for Health Insurance – ⁴ Regional Directorate of the Medical Service – ⁵ Regional Unions of Healthcare Professionals – ⁶ Patient Advocacy Groups – ⁷ Medical Science Liaisons – ⁸ Key Account Managers – ⁹ Key Institution Managers who are in contact with regional health authorities and payers and who can propose hospital centers to participate, for instance, to a local public health initiative on a given pathology – ¹⁰ Clinical Research Assistant

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Irrespective of the hospital center, the strategy crafted by pharma companies should have a favorable impact on one or several key performance drivers

**Strategic levers at hospital key account (1/2)**

- To boost their hospital performance, pharma companies can activate several internal drivers:
  - The listing on formularies under the KAM responsibility (1)
  - The prescription for inpatients (2), discharged patients (3) and outpatients (4) under the Med Reps responsibility and the activities of MSLs

- Pharma companies may also act at the level of hospital external influencers such as:
  - National or regional purchasing groups through KAMs, along with collaborators such as: head of KAMs, commercial director
  - Health authorities, health insurers and regional branches of PAGs through KIMs
  - Regional branches of learning societies through MSLs

**Key performance drivers for pharma companies**
- Listing on formularies
- Prescriptions for inpatients
- Prescriptions for discharged patients
- Prescriptions for outpatients

**In-field collaborators of pharma companies**
- Managing director
- Unit heads
- Department heads
- Financial director
- Pharmacists
- Nurses
- Physicians

**Multiple external Influencers**
- Purchasing groups
- Health authorities
- Health insurers
- PAGs
- Learning societies

Sources: Smart Pharma Consulting

¹ Patient Advocacy Groups — ² Through the therapeutic guidelines they may publish
To get the expected return on investment from hospital key account management, pharma companies should focus on five critical success factors:

**Strategic levers at hospital key account (2/2)**

**Expected impact from pharma company perspective**

**Critical success factors**

- **#1:** The services (solutions) proposed should be tailored to important needs / wants of the most influential stakeholders of the hospital center.

- **#2:** The partnership should lead to tangible and long-term “win-win” outcomes for both, the hospital center and the pharma company.

- **#3:** The services should be perfectly planned and executed, while being carefully monitored with specific KEIs\(^1\) and KPIs\(^2\) to deliver the expected joint value.

- **#4:** The services should be clearly communicated by the collaborators of the pharma company and related to its product portfolio.

- **#5:** Each hospital key account should be managed in a coordinated manner by cross-functional multidisciplinary internal and external stakeholders.

---

The specific management of hospital key accounts by pharma companies will generate extra costs due to the proposed services but should generate more sales, more profits and possibly higher profitability than a standard account management.

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Sources: Smart Pharma Consulting

\(^1\) Key Execution Indicators – \(^2\) Key Performance Indicators
KAMs are essential to get pharma companies products listed and bought by hospital centers and to ensure the proper coordination of activities carried-out by in-field teams

### Role and core activities: Introduction

<table>
<thead>
<tr>
<th>Role</th>
<th>Key activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>KAMs are one of pharma companies in-field collaborators(^1) interacting with hospital centers to develop their business over the long-term by ensuring the listing of their products and by developing associated services to optimize their value, and their probability to be purchased at a fair price.</td>
<td>Coordinated management</td>
</tr>
<tr>
<td>KAMs are best placed, due to their focused interactions with hospital pharmacists and cross-functional responsibilities, to raise the level of knowledge and understanding of each hospital center, regarding their:</td>
<td>Drug-related services</td>
</tr>
<tr>
<td>- Key objectives</td>
<td>Priming of tenders</td>
</tr>
<tr>
<td>- Strategic priorities</td>
<td>Drug commercial policy</td>
</tr>
<tr>
<td>- Key issues</td>
<td></td>
</tr>
<tr>
<td>- Organization (i.e. decision-making process, role and influence of the hospital director, financial director, medical director, heads of medical departments, information system director, etc.)</td>
<td></td>
</tr>
<tr>
<td>- KAMs have most often a background of first-line manager(^2) and are in general affiliated to the commercial department</td>
<td>In general, services proposed and delivered by KAMs are related to drug supply, drug delivery, commercial policy and focused at hospital pharmacists</td>
</tr>
</tbody>
</table>

---

\(^1\) Amongst other field teams we can mention: Medical Reps, MSLs (Medical Science Liaisons), KIMs (Key Institution Managers) – \(^2\) It is important to note that competent Medical Reps or 1st line Managers do not make necessarily competent KAMs. The skill set required for key account management role is much broader.
The complexity of hospital KAMs role lies in the fact that they must deal with multiple internal and external stakeholders having different needs and priorities

Key Institution Managers in charge of relations with regional health authorities and payers and, in some pharma companies, with local / regional politicians too –  

- Market access department (e.g. health economic specialists)
- Public affairs department (KIMs)
- Commercial department (in charge of responding to calls for tenders)
- Manufacturing and supply chain departments
- Medical affairs department (Medical manager, MSLs, CRAs)
- Patient program department
- Marketing department (marketing managers, product managers)
- Sales forces (1st line managers and medical reps)

External stakeholders

At regional / local level
- Regional Health Agency (ARS)
- Observatory of Drugs, Medical Devices and Innovation (OMEDIT)
- Primary Fund for Health Insurance (CPAM)
- Regional Directorate of the Medical Service (DRSM)
- Regional Unions of Healthcare Professionals (URPS)

At hospital level
- Managing director
- Finance director
- KOLs and other physicians
- Nurses
- Pharmacists
- Procurement manager

Integrating role to build an attractive value proposition

Orchestrating role to ensure a perfect execution of proposed services

Sources: Smart Pharma Consulting

¹ Key Institution Managers in charge of relations with regional health authorities and payers and, in some pharma companies, with local / regional politicians too  
² Medical Science Liaisons  
³ Clinical Research Assistants
The 5 key activities carried out by hospital KAMs are very similar from one company to another one

### Key activities

<table>
<thead>
<tr>
<th>Key activities</th>
<th>Description</th>
</tr>
</thead>
</table>
| Listing                      | • Coordination with Med Reps and MSLs to convince prescribers, members of the hospital listing committee, to get the company products listed and to help them fill up the dossier to motivate the listing of the concerned products\(^1\)  
  • Coordination with other KAMs to deliver the same information when decision-makers, for a given call for tenders, belong to purchasing groups at national (e.g. UNI-HA), regional and local (e.g. Hospital Territory Groups) levels  
  • It is essential to anticipate and work upstream with these different decision makers, in a coordinated manner \(^2\)                                                                 |
| Tender priming               | • Tender priming requires a coordinated approach led by the KAMs and based on tangible differentiating points to motivate a more favorable design of lots called for tenders                                                                                                                                                  |
| Commercial policy            | • The commercial policy is set with or without prior agreement  
  • Analysis of earlier calls for tenders provides information to potentially adjust prices for the others to come  
  • KAMs are also involved in negotiated contracts to set the commercial terms \(^3\)                                                                                                                                                                           |
| Drug-related services        | • KAMs can propose drug-related services which can count up to ~20% of the final mark in the evaluation of the bids for calls for tenders, as Corporate Social Responsibility initiatives can do (up to 10%)  
  • Certain companies bring their support and propose solutions to hospital centers to improve their efficiency (e.g. revision of terms of payment, conditions of supply, day care organization)                                                                                     |
| Coordinated management       | • To support the coordination of hospital centers and especially of key accounts, some pharma companies have developed a “key account plan” but, for compliance reasons, the KAMs, KIMs, MSLs and Med Reps sections are not shared on the same document or partially shared (e.g. Intranet with shared and non-shared sections)  
  • The KAM is key to raise the knowledge and understanding of hospital centers, especially if he maintains good relationships with hospitals pharmacists who, in general, have a privileged position \(^3\)                                                                 |

\(^1\) The dossier includes information such as: the number of patients, the therapeutic value, the economic impact, etc.  
\(^2\) Depending on the pharma companies, a prior agreement may be required at affiliate or even corporate level, before offering a price to hospital centers in the case of calls for tenders or negotiated contracts  
\(^3\) The KAM is also involved in the bidding process to negotiate the commercial terms.
The number of KAMs per company is mainly driven by the size of the hospital-only product portfolio and to the organizational model which has been chosen.

### Organization and targeted clients

<table>
<thead>
<tr>
<th>Companies</th>
<th>Model</th>
<th>FTEs(^2)</th>
<th>Portfolio of hospital-only drugs</th>
<th>Target clients</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Exclusive</td>
<td>15</td>
<td>Broad</td>
<td>Hospital pharmacists</td>
</tr>
<tr>
<td>B</td>
<td>Exclusive</td>
<td>4</td>
<td>Narrow</td>
<td>Hospital pharmacists</td>
</tr>
<tr>
<td>C</td>
<td>Hybrid(^1)</td>
<td>12</td>
<td>Broad</td>
<td>Hospital pharmacists (to a lesser extent have an activity with ARS and OMEDITs)</td>
</tr>
<tr>
<td>D</td>
<td>Exclusive</td>
<td>9</td>
<td>Intermediate</td>
<td>Hospital pharmacists</td>
</tr>
</tbody>
</table>

**Survey Outcomes**

**Hospital & Institution Relationships in Regions**

**Hospital KAMs**

---

Sources: Smart Pharma Consulting

\(^1\) Organizational model: some companies have opted for a hybrid model in which the same collaborator ensures the role of KAM and KIM (Key Institution Manager) at the same time

\(^2\) Full Time Equivalent
KAMs and departments in charge of responding to calls for tenders must collaborate closely to optimize their chances to win calls for tenders

Response to calls for tender department

- Monitoring of public calls for tenders published in the Official Gazette (with the possible support of specialized agencies such as MEDImarket)
- Contact of hospitals or purchasing groups to clarify requirements specifications, if needed…
- … or to understand why the company products have not been called, if it is the case
- Preparation of the administrative dossier
- Quantitative and qualitative analysis of the tendering results that are useful to prioritize the in-field collaborators activity and draw key learnings for the new calls for tenders to come

Average headcount: 3 to 7 collaborators, depending on the size of the product portfolio concerned by call for tenders

KAMs

- The KAMs will review the list of lots that are called for tenders
- They will collect qualitative and quantitative information, mainly through hospital pharmacists in charge of drugs procurement, to adjust the therapeutic and technical specificities of their products and the associated services they want to highlight
- They are responsible for setting the commercial policy, with a degree of autonomy which is very different from one company to another
- Based on the analysis of the information collected by the response to calls for tender department and by them, they may revise their price for the new calls for tenders to come

Survey Outcomes

1 In one specific company, the KAM requires the prior agreement of the corporate commercial department. Another company has set up a validation committee at affiliate level
Regional Key Institution Managers role is focused at ARS\(^1\), OMEDIT\(^2\), CPAM\(^3\), DRSM\(^4\), URPS\(^5\) who can have an influence on hospital centers decisions related to drugs

**Role and key activities**

<table>
<thead>
<tr>
<th>Role</th>
<th>Key activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ The KIMs role is to interact with regional/local health institutions (e.g. ARS, OMEDIT, CPAM, DRSM, URPS) and for certain companies with local politicians (e.g. Members of Parliament, Senators, Mayors) to optimize the conditions of use of the key products marketed by the pharma company they work for</td>
<td>▪ Project Management</td>
</tr>
<tr>
<td>▪ Thus, KIMs do not promote products</td>
<td>▪ Information sharing re. health economy</td>
</tr>
<tr>
<td>▪ KIMs may also be responsible for improving the reputation of their company by carrying out various initiatives that are likely to have a positive impact on public health at a regional/local level</td>
<td>▪ Facilitation of working sessions</td>
</tr>
<tr>
<td>▪ KIMs may have different backgrounds (e.g. marketing, sales, market access) and are affiliated, in general, either to the commercial department or the market access department</td>
<td>▪ Information sharing re. new products or new indications</td>
</tr>
<tr>
<td>▪ They need to have a solid knowledge and understanding of the healthcare system at national, regional and local levels</td>
<td>To carry out these activities, KIMs interact with health institutions by calling on them, inviting them to symposiums and proposing them or co-building with them healthcare projects</td>
</tr>
<tr>
<td>▪ They must be able to manage projects</td>
<td></td>
</tr>
</tbody>
</table>

Sources: Smart Pharma Consulting

\(^1\) Regional Health Agency – \(^2\) Observatory of Drugs, Medical Devices and Innovation – \(^3\) Primary Fund for Health Insurance – \(^4\) Regional Directorate of the Medical Service – \(^5\) Regional Unions of Healthcare Professionals
KIMs activities consist in sharing information to raise the interest of institutions about their company portfolio, the disease they address and in managing healthcare projects.

**Model – staffing – key activities and target clients**

<table>
<thead>
<tr>
<th>Companies</th>
<th>Model</th>
<th>FTEs(^2)</th>
<th>Key activities</th>
<th>Target clients</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Exclusive</td>
<td>5</td>
<td>Information sharing re. the evolution of the product “pipeline” of the company and the new coming indications for existing products</td>
<td>OMEDITs – ARS – Regional buying groups – Hospitals</td>
</tr>
<tr>
<td>B</td>
<td>Exclusive</td>
<td>4</td>
<td>Calls and meeting during regional events</td>
<td>OMEDITs – Hospitals (pharmacists and sometimes hospital directors)</td>
</tr>
<tr>
<td>C</td>
<td>Hybrid(^1)</td>
<td>12</td>
<td>Complex project management in regions as a KIM <em>(and hospital interaction management as a KAM)</em></td>
<td>OMEDITs – URPS – ARS – Hospitals</td>
</tr>
<tr>
<td>E</td>
<td>Exclusive</td>
<td>3</td>
<td>Project management (e.g. support to the development of a telemedicine program)</td>
<td>Specialist physicians – OMEDITs – URPS</td>
</tr>
<tr>
<td>F</td>
<td>Exclusive</td>
<td>3</td>
<td>Expertise sharing re. patient care, public health, disease / risk factors prevention (e.g. vaccination campaigns, smoking)</td>
<td>In-field collaborators (i.e. Med Reps, MSLs) who implement the projects at regional/local level</td>
</tr>
<tr>
<td>G</td>
<td>Hybrid(^1)</td>
<td>5</td>
<td>Health economic projects or information sharing as a KIM <em>(hospital interaction management as a KAM)</em></td>
<td>OMEDITs – DIM(^3) – ARS</td>
</tr>
</tbody>
</table>

Sources: Smart Pharma Consulting

\(^1\) Organizational model: some companies have opted for a hybrid model in which the same collaborator ensures the role of KIM and KAM at the same time

\(^2\) Full Time Equivalent

\(^3\) Information System Director at hospital level
Regional institutions are little inclined to interact or collaborate with pharma companies, unless they propose and contribute to a public healthcare project of interest to them.

### Mutual expectations between KIMs and targeted clients

<table>
<thead>
<tr>
<th>Target clients</th>
<th>Importance L – M – H*</th>
<th>Accessibility L – M – H*</th>
<th>Expectations of targeted clients from pharma companies</th>
<th>Expectations of pharma companies from targeted clients</th>
</tr>
</thead>
<tbody>
<tr>
<td>OMEDIT¹</td>
<td>H</td>
<td>M</td>
<td>▪ Information sharing regarding products marketed by the companies, especially for new products or new indications of products yet marketed</td>
<td>▪ Getting an opinion / advice before implementing a project to evaluate the benefit of a drug or a therapeutic strategy at the regional level</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>▪ Facilitation of early access for innovative drugs (e.g. screening of patients with biomarkers)</td>
</tr>
<tr>
<td>CPAM²</td>
<td>M</td>
<td>L</td>
<td>▪ No expectations</td>
<td>▪ To have the possibility to inform the CPAM re. new indications, prices, etc. for a product to avoid them to convey erroneous information to physicians that could negatively impact its performance</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>▪ CPAM distrust pharma companies and therefore do not want to interact with their collaborators</td>
<td></td>
</tr>
<tr>
<td>DRSM³</td>
<td>M</td>
<td>L</td>
<td>▪ No expectations because they distrust pharma companies</td>
<td>▪ To have the possibility to meet them to address specific problems about products indications, use, etc.</td>
</tr>
<tr>
<td>URPS⁴</td>
<td>M</td>
<td>M</td>
<td>▪ Provide an organizational and a financial support to carry out trainings, screening campaigns at regional level</td>
<td>▪ URPS are a useful relay to inform and mobilize their members to participate to healthcare projects (e.g. screening campaigns, initiatives to improve adherence of patients to treatments)</td>
</tr>
<tr>
<td>ARS⁵</td>
<td>M</td>
<td>L</td>
<td>▪ Limited or no contact, because they do not want to collaborate with pharma companies or because the latter are not a priority for them</td>
<td>▪ To set up healthcare projects and get their approval</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>▪ Convince ARS to allocate specific resources (financial and/or human) for a better management of the diseases for which the company products are indicated</td>
</tr>
</tbody>
</table>


Survey Outcomes

Sources: Smart Pharma Consulting

¹ Observatory of Drugs, Medical Devices and Innovation – ² Primary Fund for Health Insurance – ³ Regional Directorate of the Medical Service – ⁴ Regional Unions of Healthcare Professionals – ⁵ Regional Health Agency
Depending on the project, regional KIMs can propose a scientific, logistics or financial support to public healthcare projects or projects to improve the proper use of drugs.

**Examples of projects carried out with regional institutions**

<table>
<thead>
<tr>
<th>Project #1: The Immunization Day</th>
<th>Project #2: Drug Fact Sheet</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objectives</strong></td>
<td></td>
</tr>
<tr>
<td>▪ Scientific support</td>
<td>▪ Writing of a drug fact sheet for a new product…</td>
</tr>
<tr>
<td>▪ Logistics support</td>
<td>▪ … while transitioning from the ATU (Temporary Use Authorization) status to the post-ATU one</td>
</tr>
<tr>
<td>▪ Formatting of messages</td>
<td>▪ Set up of working groups in regions</td>
</tr>
<tr>
<td><strong>Partners</strong></td>
<td></td>
</tr>
<tr>
<td>▪ ARS</td>
<td>▪ OMEDIT</td>
</tr>
<tr>
<td>▪ CPAM</td>
<td></td>
</tr>
<tr>
<td><strong>Duration</strong></td>
<td></td>
</tr>
<tr>
<td>▪ 1 month</td>
<td>▪ 2 months</td>
</tr>
<tr>
<td><strong>Conclusion</strong></td>
<td></td>
</tr>
<tr>
<td>▪ Impact on medical practices: raise the awareness re. the pharmaceutical conciliation(^1) especially during the patient transition from hospital to ambulatory care</td>
<td>▪ This drug fact sheet has shown to be useful especially to inform the pharmacists…</td>
</tr>
<tr>
<td>▪ Publication of the results</td>
<td>▪ … and thus to guarantee the proper and safe use of this new drug</td>
</tr>
</tbody>
</table>

\(^1\) Information sharing amongst healthcare professional regarding a given patient to avoid errors while prescribing and/or dispensing drugs to patients.
These two projects show the ability of pharma companies to bring together diverse expertise to produce recommendations or carry out pilot projects related to healthcare.

### Examples of projects carried out with regional institutions

#### Project #3: Innovation in Oncology

- **Objectives**
  - Multi-disciplinary experts (oncologists, surgeons, pharmacists, PAGs, economists, lawyers, pharma companies, etc.) have written a manifesto with 30 propositions to favor innovation in the oncology field.

- **Partners**
  - 113 experts

- **Duration**
  - 2 years

- **Conclusion**
  - Increase awareness regarding key topics such as: delays in access to innovation, methods to evaluate innovation, real-world data processing.
  - This manifesto has been handed over by KIMs while meeting healthcare institutions in regions.

#### Project #4: AMD<sup>1</sup> Screening in Region

- **Objectives**
  - Screening of AMD in the Northern region of France (Hauts-de-France).

- **Partners**
  - CPAM
  - Healthcare network
  - URPS of pharmacists
  - Teaching hospital

- **Duration**
  - 4 weeks

- **Conclusion**
  - Out of the 1,200 patients diagnosed, 250 had a stage 1 AMD and 12 have been treated, urgently.
  - The ARS agreed to deploy this project across the region, but without the support of the pharma company.

---

<sup>1</sup> Aged Macular Degeneration
Projects managed by regional KIMs may (should) contribute to raise the value of the response to the calls for tenders, as illustrated in this example.

**Examples of projects carried out with regional institutions**

**Project #5: Hospital Day Care Management**

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Institutions</th>
<th>Duration</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Measurement of time spent by patient</td>
<td>• Hospital centers</td>
<td>• 3 to 6 months (delay due to the time required to get the agreement from the hospital director)</td>
<td>• This has enabled hospital centers to improve their efficiency while managing drug perfusion to patients</td>
</tr>
<tr>
<td>• Search of solutions to reduce the cost of hospital day care against diagnosed-related groups (DRG)</td>
<td></td>
<td></td>
<td>• This service has been highlighted in the responses to calls for tenders</td>
</tr>
<tr>
<td>• Methodological contribution to the hospital center</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Survey Outcomes**

*Sources: Smart Pharma Consulting*
The services proposed must offer tangible benefits to the targeted customer and to the pharma company by improving access and usage of its products.

Examples of services for hospital centers and regional institutions:

- **Co-creation of a specific program** to increase the number of referred patients, leading to more activity for the hospital center, more drug prescriptions for the pharma company and more income for both.

- **Co-development of a patient registry** and offering of a technical support to collect and analyze data to help the hospital center increase medical outcomes in a specific disease covered by the pharma company.

- **Creation and funding of a support program** to improve the adherence of patients to their treatment in exchange of a preferred supplier status on the hospital drug formulary.

- **Design and implementation of a specific process to reduce** the distribution and inventory costs for both, the hospital center and the pharma company.

- **Help the key account re-engineer** the journey of hospitalized patients to reduce the duration of their stay and the time allocated by the HCPs to look after them.

Sources: Smart Pharma Consulting
From the pharma company perspective, the value of the proposed services should be translated into higher product sales and associated profits

Impact of services on pharma company performance

The ultimate objective of services proposed to hospital centers or regional institutions is to fulfill their highly valued needs to enhance – directly or indirectly – their preference for the products marketed by the pharma company.

- KAMs and KIMs should communicate once or twice a year information about their company (e.g. R&D news, CSR\(^1\) initiatives, specific services delivered, etc.) to hospital stakeholders and regional institutions.

- The direct or indirect\(^2\) impact of services on products will be objectivized by the positive evolution of their performance drivers in hospital centers:
  1. Listing on formularies
  2. Prescription for inpatients
  3. Prescription for discharged patients
  4. Prescription for outpatients

- The perceived value of the proposed services by KAMs and/or KIMs at hospital center level will depend on their ability to:
  - Reduce hospital costs
  - Improve operational management
  - Improve medical management…

- … and on their quality of execution:
  - Planning
  - Execution per se
  - Monitoring

- These services should have a positive impact on corporate reputation and products perception of the pharma company.
The activities of in-field collaborators interacting with the same hospital center should be integrated in a single key account management plan, including separated sections

**Integrated Key Account Management Plan**

**MSL Section**
- **Key clients:** KOLs
- **Key objectives:** build strong and sustainable relationships to develop advocacy at hospital level and beyond
- **Key activities:** interactions with KOLs, scientific lectures at congresses, symposia, staff meetings, support of research clinical trials, training of speakers and collaborators from marketing and sales teams, competitive intelligence initiatives, etc.

**KAM Section**
- **Key clients:** hospital pharmacists, purchase managers, director
- **Key objectives:** facilitate the hospital listing of drugs and maximize the chances to win the calls for tenders and get a fair price when products are bought through negotiated contracts
- **Key activities:** develop close relationships with hospital pharmacists, prime calls for tenders, highlight the value of the products and of their associated services regarding drug supply and management, negotiate payment terms, coordinate MSLs, Med Reps and KIMs activities per key account

**Marketing & Medical Rep Section**
- **Key clients:** physicians and pharmacists
- **Key objectives:** increase prescriptions
- **Key activities:**
  - **Marketers:** brand preference strategy crafting leveraging products attributes, perceived quality of associated services and corporate reputation
  - **Medical reps:** calls, invitations to medical meetings and congresses and other services to boost preference

**KIM Section**
- **Key clients:** health authorities¹, payers¹, hospital directors, regional and local politicians, PAGs
- **Key objectives:** create the conditions to grow the therapeutic areas covered by the company products, ensure their proper use and participate to strengthen the company reputation at regional level
- **Key activities:** share relevant health economic information, new indications, new products information, propose specific projects (e.g. medico-economic studies to increase the access to the products, patient support programs to improve adherence to treatments, etc.)

---

¹ At regional or local level

Sources: Smart Pharma Consulting
KAMs and KIMs must have an in-depth understanding of hospital centers and of regional healthcare environment and be able to build trusted relationships

Profile & competences of “best-in-class” hospital KAMs & KIMs

1. Personality
- Enthusiastic & Entrepreneur
- Self-confident & Daring
- Curious & Creative
- Long-term focus
- Empathic & Emotional
- Team player

2. Knowledge
- Regional healthcare environment
- Health economic basic principles
- Hospital organization, network of influencers & decision-makers
- Stakeholders profile, field of interest, needs and wants
- Complex project management

3. Analytical Skills
- Understanding of stakeholder expectations
- Selection of most valuable services by hospital center
- Ability to demonstrate the value of proposed services

4. Behavior
- Organizational skills
- Orchestration of in-field collaborators\(^1\) interacting with key hospital centers
- Search for continuous improvement of stakeholder satisfaction

\(^1\) Medical, marketing, sales people and KIMs (Key Institution Managers)
The performance and activities of KAMs and KIMs are evaluated with the help of KPIs and KEIs respectively, as indicated by interviewed senior executives.

### Survey Outcomes

<table>
<thead>
<tr>
<th>Key Performance Indicators (KPIs)</th>
<th>Key Execution Indicators (KEIs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ <strong>Hospital Listing</strong> (Yes / No)</td>
<td>▪ <strong>Number of contacts</strong> (F/F. phone, e-mails)</td>
</tr>
<tr>
<td>▪ <strong>Calls for tenders</strong> (Won / Lost)</td>
<td>▪ <strong>Activity planning</strong> (e.g. quality of tendering planning)</td>
</tr>
<tr>
<td>▪ <strong>Average price level</strong> (actual vs. budgeted)</td>
<td>▪ <strong>Quality of execution of the action plan</strong> (e.g. % of applications sent on time for calls for tenders)</td>
</tr>
<tr>
<td>▪ <strong>Sales performance</strong> (Units sold per month per hospital center)</td>
<td>▪ <strong>Project management</strong> (compliance with project deadlines, satisfaction of targeted customers re. the project development and execution)</td>
</tr>
<tr>
<td>▪ <strong>Savings due to optimized management of products whose patent has expired</strong></td>
<td>▪ <strong>Coordination of the in-field team members activity per hospital center</strong> (e.g. frequency and quality of interactions, relevance of joint-activities, respect of compliance rules)</td>
</tr>
<tr>
<td>▪ <strong>Customer preference survey</strong> (Brand Preference Mix(^1))</td>
<td></td>
</tr>
<tr>
<td>▪ <strong>Reputation assessment survey</strong> (Pharma Reputation Index(^1))</td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) See our position paper “KPIs & KEIs for success” on our website: www.smart-pharma.com

Sources: Smart Pharma Consulting

Blue text concerns more specifically KAMs
Irrespective of their competence, KAMs and KIMs should dramatically improve their performance if they implement our recommendations in a rigorous and systematic way.

**Recommendations**

**Objective**
- Hospital KAMs and regional KIMs **priority** is to contribute to raise **preference** of stakeholders **for their product** portfolio.

**Strategy**
- **Hospital KAM** job should be to obtain the **listing** of company products at hospital centers, contribute to get **purchased** at a **fair price** by **highlighting** the competitive **advantages** of **products** and "offering" **associated services** re. supply.
- **Regional KIM** job should be focused at **contributing to public health initiatives** (e.g. screening, adherence programs) re. diseases covered by the company products, at **ensuring corporate communication** (e.g. pipeline, healthcare services, CSR projects) to **improve** the **reputation** of the **company** and at **raising** the **value** of the **products** by sharing or generating health **economic data** at regional and/or hospital level(s).

**Organization**
- Hospital KAM and regional KIM jobs should **ideally be combined** to get a **greater flexibility** in terms of resource allocation and to increase synergy.
- The following **skills** should be strongly developed:
  - **Strategic vision** to help, for instance, hospital general managers or hospital directors meet their objectives
  - **Soft skills** (e.g. interpersonal skills, problem solving, adaptability, teamwork, creativity)
  - **Technical knowledge** (e.g. healthcare system and hospital management, diseases, products, health economics)
  - **Management knowledge** to carry out projects and coordinate multi-disciplinary teams.
Strategic KOL Engagement Planning…

Concepts Methods & Tools

… For a better Efficacy & Efficiency

Position Paper
May 2019
This position paper proposes guidelines to help pharmaceutical companies partner with KOLs to better support the development and the marketing of their products.

**Context & Objective**

- **KOLs** are part of the means used by pharma companies to:
  - Develop their products through pre-clinical and clinical trials
  - Disseminate information (scientific, medical, therapeutic, etc.) to raise health authorities, payers, HCPs (Health Care Professionals), PAGs (Patient Advocacy Groups), individual patients awareness to optimize the positioning and the usage of their products

- **This position paper:**
  - Reviews the best practices in terms of KOL engagement
  - Proposes a simple but rigorous approach and…
  - … a set of practical tools…
  - … to recruit, engage and manage KOLs

This position paper has been written, assuming that it is not illegal nor reprehensible to collaborate with medical thought leaders to influence other stakeholders opinion and behavior vis-à-vis a medical practice or a given medicine, provided it is in the best interest of patients.

Sources: Smart Pharma Consulting

\(^1\) In this position paper, the definition of KOL is limited to influential physicians
KOLs have the potential to influence their peers, but also other stakeholders in a specific area, at global, international, national and local levels

**Working definitions (1/2)**

**KOL (Key Opinion Leader)**
- KOLs are also called: Key Experts, Key Therapeutic Area Experts, Key Scientific Experts, Thought Leaders, Influencers, depending on the companies.
- KOLs are **recognized** physicians with an **expertise in a specific field** (e.g. oncology, endocrinology, epidemiology, biostatistics, etc.)...
- … and can **influence the opinion and the medical practice** (e.g. treatment scheme, prescribing habits, preference for a given product, etc.) of their peers (specialists or GPs).
- KOLs contribute also to **modify medical guidelines** when they are members of learned societies or when they advise health authorities.
- Their influence can be global, international, national or local.
- Other stakeholders are also considered as KOLs\(^1\)

**Pyramid of influence & types of influencers**

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**Sources:** Smart Pharma Consulting

\(^1\) Such as members of governments, of health authorities, of learned societies, of patient advocacy groups, journalists, pharmacists, nurses, etc.
Strategic KOL Engagement Planning is essential for pharma companies to ensure an effective, efficient and sustainable relationship with KOLs

Working definitions (2/2)

**KOL Engagement**

- KOL engagement is a **process** in which pharma companies **build** and **maintain constructive** and **sustainable relationships** with KOLs.
- KOL engagement is **essential** for understanding their **wants** and **needs**; and **may** result in implementing ideas that **benefit** both **KOLs** and **pharma companies**.
- Engaging with KOLs **occurs** when pharma companies want to **consider** the **views** and **involvement** of **KOLs** in making and implementing a scientific or medical decision…
- … **which might** have an indirect **business impact**.
- Pharma companies should **initiate open, two-way dialogue, seeking solutions** to issues of mutual interest.

**Strategic KOL Engagement Planning**

- Considering the **increasing complexity** of the pharmaceutical **environment** and of **pharma companies** organizations, it is essential to **plan** and **organize** the **interactions with KOLs**.
- Thus, pharma companies should develop **Strategic KOL Engagement Plans** to ensure, as a general rule, that KOL Engagement **initiatives**:
  - **Support** the Critical Success Factors (CSF) to fulfill the corresponding Strategic Imperatives (SI) of the related product.
  - Are put in a **mid- to long-term perspective** to **build** a **sustainable win-win relationship**.
  - Are carried out in a **coordinated manner** across the company departments and from headquarter to affiliates to **guarantee** an **optimal efficiency**

Sources: Roche internal documents (2015) – Smart Pharma Consulting

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1 People from different departments (e.g. medical, marketing, sales, etc.) can be in regular contact with the same KOL.
More and more pharma companies are adopting an integrated strategic approach of their relationship with KOLs, based on their product position on their life cycle

Types of KOL engagement

- According to a study carried out in 2017 by Arx Research, through interviews of 47 executives from medical departments of 34 life science organizations, across 15 countries:
  - 70% of companies indicate that their strategy to engage with KOLs is based on the position of the product on its life cycle, while the remaining 30% adopt an ad-hoc approach
  - 24% of surveyed companies engage with KOLs during pre-clinical phases of the product development and…
  - … 41% begin developing relationships at phase III of their product life cycle, or after
- KOLs exposed to early research and development phases will better support the products due to:
  - A better understanding of the underlying science
  - A better commitment and interest in outcomes

Sources: Arx Research (2017) – Smart Pharma Consulting analyses
The strength of KOL engagement will strongly depend on the quality of scientific evidence related to the product as well as on corporate and product perception

**KOLs engagement & Influencing factors**

- From preclinical to phase II studies, Global KOLs are engaged to carry out scientific and clinical activities.
- At phase III level, Global, International and National KOLs are mainly involved in clinical studies and in disseminating scientific information to physicians communities.
- While preparing the launch of their products or of new indications, pharma companies may engage KOL to support the preparation of the marketing authorization and of the price & reimbursement dossiers.
- At launch time, pharma companies usually shift the balance of their focus to national and local KOLs.
- The quality of the scientific evidence is critical to establish strong and effective relationships with KOLs.
- Corporate reputation and product recognition are also essential to expect a clear commitment from KOLs.

**Factors influencing KOL relationships**

- Competitive landscape: 4.91
- Therapeutic area: 4.95
- Product recognition: 5.74
- Corporate reputation: 5.86
- Quality of scientific evidence: 8.00

Sources: Arx Research (2017) – Smart Pharma Consulting analyses
The hybrid and centralized management of KOLs are viewed as optimal by interviewees as they enable better coordinated and more consistent interactions.

**KOLs management by pharma companies**

- **KOL Management responsibility at pharma companies**
  - Medical Affairs: Functional 94%, Budget 87%
  - Clinical Affairs/Operations: Functional 55%, Budget 39%
  - Marketing: Functional 52%, Budget 55%
  - R&D: Functional 32%, Budget 29%

- **KOL Management organization at pharma companies**
  - Current N=33: Hybrid 40%, Centralized 33%, Decentralized 27%
  - Optimal N=29: Hybrid 11%, Centralized 38%, Decentralized 33%, Other 48%

- **Functional and budget responsibility for KOL management are mainly in the hands of Medical Affairs departments**

- **Decentralized organizations are used by 40% of companies but recommended by only 3% of them due to lack of coordination and consistency**

Sources: Best Practices, LLC (2014 & 2016) based on 33 companies, amongst which: AbbVie, Amgen, Bayer, Genentech, Genzyme, Janssen, Merck & Co, Pfizer, Roche – Smart Pharma Consulting analyses

*One respondent considers there is no ideal system to manage KOLs. It depends on the business needs*
If KOLs services are mainly focused on clinical research, clinical advisory boards and disease state awareness exchanges; their impact is most often not formally evaluated.

Main KOLs services & assessment

**Most important services carried out by KOLs**

<table>
<thead>
<tr>
<th>Service</th>
<th>N=28</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marketing advisory board</td>
<td>56</td>
<td></td>
</tr>
<tr>
<td>Consulting opportunities</td>
<td>64</td>
<td></td>
</tr>
<tr>
<td>Off-label discussion</td>
<td>66</td>
<td></td>
</tr>
<tr>
<td>Speaker training</td>
<td>78</td>
<td></td>
</tr>
<tr>
<td>Peer-to-peer presentations</td>
<td>83</td>
<td></td>
</tr>
<tr>
<td>Disease state awareness</td>
<td>105</td>
<td></td>
</tr>
<tr>
<td>Medical advisory boards</td>
<td>107</td>
<td></td>
</tr>
<tr>
<td>Clinical research</td>
<td>114</td>
<td></td>
</tr>
</tbody>
</table>

Mean score: 75

**Evaluation of KOL Management & Engagement**

<table>
<thead>
<tr>
<th>Service</th>
<th>N=24</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other</td>
<td>21%</td>
<td></td>
</tr>
<tr>
<td>Return on investment</td>
<td>8%</td>
<td></td>
</tr>
<tr>
<td>KOL utilization level</td>
<td>8%</td>
<td></td>
</tr>
<tr>
<td>No evaluation</td>
<td>13%</td>
<td></td>
</tr>
<tr>
<td>KOL feedback</td>
<td>25%</td>
<td></td>
</tr>
<tr>
<td>No formal evaluation</td>
<td>29%</td>
<td></td>
</tr>
</tbody>
</table>

Note: Score based on the average importance rating (0 to 5) multiplied by the number of respondents per activity

- Clinical research support, participation to medical advisory boards and disease state awareness are viewed as the most important KOLs activities
- There is no formal nor systematic measurement of the impact of KOLs engagement carried out by most of the pharma companies from the panel

Sources: Best Practices, LLC (2014 & 2016) based on 33 companies, amongst which: AbbVie, Amgen, Bayer, Genentech, Genzyme, Janssen, Merck & Co, Pfizer, Roche – Smart Pharma Consulting analyses
Few of the 8 benchmarked pharma companies have put in place a systematic and formalized process to qualify and select Global KOLs

Main criteria to select Global KOLs

- **Skills**: 3
- **Membership to cooperative groups**: 3
- **Scope of influence / Reputation**: 5
- **Involvement in the crafting of guidelines**: 5
- **Publications**: 8

Data gathering

- **Process**
  - Formal process

- **Sources**
  - External agency if new TA
  - Inputs from affiliates
  - Internal / external cross-check

- **Tools**
  - Centralized database

"In case of doubts, Global Medical Affairs may contact local Medical Affairs to get their own opinion regarding a Global KOL”

Note: Behavior & personality has been mentioned by one interviewee, as well as KOLs field of interest

Sources: Interviews of 8 Senior Medical executives from Bayer, BMS, Celgene, Gilead, Janssen, MSD, Pfizer, Roche – Smart Pharma Consulting analyses

1 Therapeutic Area
According to the spontaneous statements of interviewees, Global KOLs are mainly engaged to give advice on brand positioning, produce and exchange scientific data.

**Main objectives while engaging with Global KOLs**

- **Objective setting**
  - No formal approach, based on specific KOL expertise and company needs
  - Objective alignment on product Strategic Imperatives & Critical Success Factors
    - No formal alignment / no global vision
    - Alignment on Global Strategic Brand Plan / R&D Plan / Global Medical Affairs Plan

- **Type of agreements**
  - Both types: 3
  - Mainly Partnership-based: 2
  - Mainly transactional: 3

- **Quote:**
  "While engaging with a KOL, we make sure he is interested by the project on which we want to involve him"
Global KOL engagement plans are most often not formalized for each KOL and their follow-up over time is far from being systematic

**Global KOL engagement planning & execution follow-up**

**Global KOL engagement plans**

- Yes: 3
- No: 5

“We prepare an engagement plan but by project rather than by KOL. We engage a KOL to carry out a project”

**Execution quality follow-up**

- Yes: 3
- No: 5

“In Europe, it is difficult to evaluate the performance of KOLs. It should be fact-based and not a judgement”

**Main difficulties while engaging with Global KOLs**

- Poor internal alignment and multiple contact points
- Overbooked and overused KOLs

Sources: Interviews of 8 Senior Medical executives from Bayer, BMS, Celgene, Gilead, Janssen, MSD, Pfizer, Roche
– Smart Pharma Consulting analyses
The effective KOL management requires a cross-functional team working in the same direction, in a coordinated manner, with the help of a shared information system.

**Strategic KOL Management components**

- **Coordinator (Primary Contact Point)**
  - Coordinates interactions with KOLs
  - Oversees the management system
  - Guarantees the quality of the collaboration

- **KOL Management System & Platform**
  - Stores information relative to:
    - KOLs profiles
    - KOL engagement plans
    - KOL interactions
  - Limits the access of certain medical information to commercial collaborators

- **Cross-functional Strategic Team**
  - Gathers and analyzes information across access, medical and commercial departments
  - Prioritizes the activities to be carried out by individual KOL according to the product needs and the KOL profile

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Sources: Best Practices, LLC (2014 & 2016) based on 33 companies, amongst which: AbbVie, Amgen, Bayer, Genentech, Genzyme, Janssen, Merck & Co, Pfizer, Roche – Smart Pharma Consulting analyses

1 Whenever required by the compliance rules – 2 Internal and external sources
The following 4-step approach is proposed to ensure an effective and efficient Strategic KOL Engagement Planning:

1. **Objective setting**
   - Relationships with KOLs should be defined according to the set objectives.
   - Then, the prospective KOLs should be profiled and targeted.

2. **KOL Selection**
   - Once KOLs have been selected, their interactions with the pharma company and the activities they are expected to carry out should be defined and formalized in an engagement plan.

3. **KOL Engagement**
   - The execution of the plan should be carefully monitored with the help of KPIs (Key Performance Indicators) and of KEIs (Key Execution Indicators).

4. **Monitoring**

**A 4-step approach**
At each step, the following key questions should be carefully answered to ensure the proper implementation of the proposed Strategic KOL Engagement Planning process.

**Key questions to be answered by key step**

1. **Objective setting**
   - What do we expect from KOL engagement?
   - What do KOLs expect from us?

2. **KOL Selection**
   - Who are the KOLs we want to engage with?
   - Why do we want to engage with them?

3. **KOL Engagement**
   - Which interactions should be carried out with KOLs to reach the set objectives?

4. **Monitoring**
   - How to measure the impact of KOL engagement vs. the objectives and KOL satisfaction?
The global objectives set for KOL engagements should contribute – directly or indirectly – to meet the brand strategic objectives, irrespective of its life cycle position

Strategic alignment

The global objective of KOL engagements must support one or several CSFs and thus, contribute to fulfill the strategic imperatives to reach the Brand Strategic Objective

Sources: Smart Pharma Consulting

1 Critical Success Factor
Before defining the KOL Engagement Plan, specific objectives by KOL, consistent with the Brand Strategic Objective, must be set.

1. **Global vs. individual objective setting**

   **Global objectives**
   Define precisely what is expected from KOL engagement, in terms of direct or indirect benefits for the brand under development or marketed by the pharma company.

   **Individual objectives set by KOL**
   Define specifically what is expected from each KOL to support the product and what support each KOL expects from the pharma company, on a professional standpoint.

Sources: Smart Pharma Consulting
The objective of the KOL partnership and the corresponding activities will depend on where the product is positioned on its life cycle.

**Examples of objectives along the product life cycle**

<table>
<thead>
<tr>
<th>Product life cycle</th>
<th>R&amp;D and registration phases</th>
<th>Commercial phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research &amp; pre-clinical phases</td>
<td>Phase I</td>
<td>Phase II</td>
</tr>
</tbody>
</table>

### Examples of KOL roles

1. **Identification of unmet medical needs**
2. **Identification of pharmacological targets**
3. **Advice on target product profile and labelling**
4. **Implementation of R&D activities**

- **Presentation of clinical results and of product benefits to regulators and payers**
- **Product awareness building & influence on prescribing choices**
- **Participation in medical education programs**
- **Contribution to patient management programs**
- **Real World Data generation/phase IV studies**

Sources: Adapted from GBI Research, Market Rx, by Smart Pharma Consulting

1. Through articles, lectures, etc. – 2. Through Continuous Medical Education (CME) programs – 3. Through projects carried out with patient advocacy groups (PAGs) – 4. Investigator Initiated Trials
The selection phase consists in a 4-step process leading to a pool of KOLs with whom to engage to benefit (directly or indirectly) the brand.

### Methodology

<table>
<thead>
<tr>
<th>Key questions</th>
<th>What to do?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Selection criteria</strong></td>
<td>▪ Review the relevant criteria (e.g. level of influence, scope of influence, scientific/media awareness, membership of a network, presence in Internet, etc.)</td>
</tr>
<tr>
<td>▪ What are the relevant selection criteria to be used considering the final objective?</td>
<td>▪ Select a limited number of relevant criteria</td>
</tr>
<tr>
<td><strong>KOLs profiling</strong></td>
<td>▪ Review internal / external databases to qualify KOLs</td>
</tr>
<tr>
<td>▪ What information should be collected?</td>
<td>▪ Assess the number of publications, quality of journal, the impact factor, Almetrics(^1), quotes, lectures during conferences and congresses, etc.</td>
</tr>
<tr>
<td>▪ How to collect and analyze this information?</td>
<td>▪ Map a preselection of KOLs on a matrix according to the most relevant criteria</td>
</tr>
<tr>
<td><strong>KOLs segmentation</strong></td>
<td>▪ Identify KOLs networks of collaboration and influence (e.g. cooperative groups)</td>
</tr>
<tr>
<td>▪ What is the scope of influence and the degree of interest of the KOL for the brand and the related disease(s)?</td>
<td>▪ Select the KOLs</td>
</tr>
<tr>
<td><strong>KOLs selection</strong></td>
<td>▪ Preliminarily define the types of engagement to carry out with the selected KOLs</td>
</tr>
<tr>
<td>▪ Who are the KOLs that should be engaged?</td>
<td>▪ For which kind of engagement?</td>
</tr>
</tbody>
</table>

\(^1\) Collects and collates disparate information on the online activity surrounding scholarly content
Relevant selection criteria and gathering of accurate and reliable information about the KOLs profiles are of utmost importance to optimize the value of their engagement.

**Screening process (illustrative)**

**Filter 1**
**Field of expertise**
- Oncology (medical, radiation and surgical oncology, hematology, brain cancer, etc.)
- Cardiology (hypertension, arrhythmias, heart failure, surgery, valvopathy, etc.)
- Rheumatology (osteoporosis, rheumatoid arthritis, osteoarthritis, psoriatic arthritis, etc.)
- Technical expertise (design of clinical studies, biostatistics, epidemiology, public healthcare, patients adherence, etc.)

**Filter 2**
**Level of reputation & influence**
- Reputation of the hospital/ward the KOL works for
- Reputations of the KOL (based on status, honors, publications, etc.)
- Power of influence (on peers, health authorities, PAGs\(^1\))
- Scope of influence (global, international, national, local)

**Filter 3**
**Potential interest**
- Inclination to communicate (in a neutral or positive way)
- Communication skills (written and/or verbal)

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\(^1\) Patient advocacy groups
Qualification of KOLs should be documented with reliable and real-time data collected through desk research and field research (e.g. interviews of peers, pre-identified KOLs)

How to qualify KOLs? (1/2)

<table>
<thead>
<tr>
<th>What data to collect?</th>
<th>How to collect data?</th>
<th>How to analyze data?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Education</strong> (e.g. university – hospital)</td>
<td>Internet search, direct search</td>
<td>Being head of hospital and professor is a plus</td>
</tr>
<tr>
<td><strong>Medical activity/position</strong> (e.g. specialty, medical department, status in the medical department)</td>
<td>Field research (e.g. peers, hospital pharmacists interviews, etc.)</td>
<td>Reputation of the hospital/teaching hospital or of the private institution where the KOL works should be considered</td>
</tr>
<tr>
<td><strong>Teaching activity/position</strong> (e.g. topics taught, professor, lecturer)</td>
<td>Probing by collaborators from the medical department (e.g. MSLs) and collaborators from other departments of the pharma companies (data could be stored and shared on a platform)</td>
<td>Global or International scopes of influence are preferable, in general, to national or local levels (but it depends on the objective)</td>
</tr>
<tr>
<td><strong>Field of expertise and interest</strong> (e.g. specific disease, pharmacological route, mode of action, medical technique)</td>
<td>KOL Management vendors (e.g. Truven; KOL, LLC; OpenQ; Veeva Systems)</td>
<td>Being a member of the management board of a learned society is a plus in terms of potential level of influence</td>
</tr>
<tr>
<td><strong>Membership in learned societies</strong> (titles / positions / activities) and/or in more or less structured networks</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sources: Smart Pharma Consulting

1 Medical Science Liaisons
Qualification of KOLs should be documented with reliable and real-time data collected through desk research and field research (e.g. interviews of peers, pre-identified KOLs)

### How to qualify KOLs? (2/2)

<table>
<thead>
<tr>
<th>What data to collect?</th>
<th>How to collect data?</th>
<th>How to analyze data?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Communication activities</strong></td>
<td>Review of published scientific articles (PubMed/Medline, Google scholar, Expertscape, Cochrane Library)</td>
<td>The higher the impact factor is, the better</td>
</tr>
<tr>
<td>– # articles published (impact factor(^1), Almetrics(^2), peer-/non peer reviewed journals, principal investigator (PI), etc.)</td>
<td>Evaluation of training/teaching activities and lectures by interviewing peers and collaborators of pharma companies</td>
<td>KOLs should be ideally positioned as 1(^{st}) or last author in articles</td>
</tr>
<tr>
<td>– # of training/teaching activities p.a. (CME(^3))</td>
<td>Google searching for presence and quotes on the Internet</td>
<td>A high number of training/teaching seminars and lectures is a plus</td>
</tr>
<tr>
<td>– # of lectures (congresses, symposiums, round tables)</td>
<td></td>
<td>The perceived quality of articles, training, teaching and lectures should be assessed</td>
</tr>
<tr>
<td>– Presence on the Internet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>– # of quotes by journalists in current year</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Partnership activities</strong></td>
<td>Review of past performances with the company or its competitors (e.g. probing by collaborators of the company)</td>
<td>Verbal (e.g. lectures, courses) and written communication (e.g. articles, websites)</td>
</tr>
<tr>
<td>– Types of activities (e.g. lectures, clinical investigations, advisory boards)</td>
<td>Interviews of peers</td>
<td>KOLs should express their field of interest over the long term and their expectations from an engagement with the pharma company</td>
</tr>
<tr>
<td>– With the company and its competitors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Potential level of interest (inclination to support the development/the proper use of a brand)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) It measures the average frequency with which the article has been cited in a particular year. It is used to measure the importance or rank of a journal by calculating the number of times its articles are quoted. 
\(^2\) Collects and collates disparate information on the online activity surrounding scholarly content. 
\(^3\) Continuous medical education
The following table shows a proposed approach to evaluate and rank candidate KOLs to set up a list of Top Global KOLs, that should be continuously updated.

### Scoring of candidate KOLs

<table>
<thead>
<tr>
<th>Profiling parameters</th>
<th>Prof. A</th>
<th>Prof. B</th>
<th>Prof. C</th>
<th>Dr. D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacological expertise</td>
<td>8</td>
<td>0</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Academic research</td>
<td>5</td>
<td>9</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Clinical research</td>
<td>5</td>
<td>0</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>Clinical practice</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>Scientific advisory board</td>
<td>8</td>
<td>8</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Sub-total score (A)</td>
<td>5.2</td>
<td>3.4</td>
<td>5.6</td>
<td>4.0</td>
</tr>
<tr>
<td>Publication record</td>
<td>8</td>
<td>5</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Speaker record</td>
<td>3</td>
<td>4</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>Communicate skills</td>
<td>6</td>
<td>6</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>Density of the network</td>
<td>5</td>
<td>7</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Sub-total score (B)</td>
<td>5.5</td>
<td>5.5</td>
<td>6.0</td>
<td>5.0</td>
</tr>
<tr>
<td>Impact Index$^2$ score (A x B)</td>
<td>14.3</td>
<td>9.4</td>
<td>16.8</td>
<td>10.0</td>
</tr>
<tr>
<td>KOL degree of interest</td>
<td>Moderate</td>
<td>High</td>
<td>Moderate</td>
<td>Low</td>
</tr>
<tr>
<td>Ranking</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>

- The candidate KOLs can be ranked according to their field of expertise, their associated level of recognition in these fields, and their level of awareness.
- The KOL degree of interest for the product should also be considered.
- The assessment could be done on a 10-point scale based on data coming from external providers, a panel of peers who will score each expert, combined with the internal insights available at the pharma companies level, etc.
- This approach will help make a first cut of the Top Global KOLs that should be continuously reevaluated.

1 Average of the marks obtained – $^2$ [Expertise x Awareness] / 2

---

Sources: Niche Science & Technology (2016) – Smart Pharma Consulting analyses
The proposed matrix is a useful tool to prioritize the KOLs with whom to engage and to pre-define the types of collaboration to carry out with them.

### KOL targeting – Segmentation & selection

The proposed matrix facilitates the final selection (targeting) of pre-selected KOLs based on their:
- **Impact index** (combining their degree of expertise and awareness\(^1\))
- **Potential interest**

The impact index reflects the KOLs ability to influence other stakeholders (i.e. HCPs, policy makers, payers, patients, PAGs).

The degree of interest reflects the KOLs willingness to support:
- The development of the company brand
- The proper use of the brand, once marketed

The network\(^2\) of KOLs should also be considered.

---

\(^1\) Including on Internet – \(^2\) Network of influence / collaboration amongst KOLs

Sources: Smart Pharma Consulting
To convince KOLs to partner, it is important to consider their expectations and to highlight the benefits they will draw from it in terms of professional development.

**How to convince KOLs to partner?**

### What do KOLs want through engagements?

- The selection of KOLs should consider the **benefits they can offer** to the pharma companies and the **benefits** the pharma companies can **offer to them**.

  
  **For so doing, the following questions should be addressed:**

  - Is the KOL yet a **partner** of the pharma company?
  - What has been qualitatively and quantitatively **his level of involvement**?
  - What has been **his feed-back** (level of satisfaction) from previous collaborations?
  - What is his mid- to long-term professional **ambition**?
  - What does he **expect from collaborations** with pharma companies?
  - Is he looking for a long-term partnership or a “fee-for-service” transaction?

### What should pharma companies propose to KOLs?

- Based on KOLs professional expectations, pharma companies can **propose ideas** of “win-win” **activities** to be carried out through engagements.

  - The **benefits** the KOLs will draw in terms of **personal awareness** and **competence development** through the engagement should be emphasized:

    - **Opportunity to participate in** publication of articles, interviews in media, presentations during congresses, lectures during medical meetings, etc.
    - **Provide expert opinion/guidance and/or…**
    - **… opportunity to participate in clinical research (e.g. clinical trials) or to carry out IITs**
    - **Professional development** through the **access to recent information**, to **high education programs**, by working in new research/medical areas, etc.

---

Sources: Smart Pharma Consulting

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1 Investigator Initiated Trials—2 Especially for Rising Opinion Leaders
Pharma companies should be able to manage dynamically their selected KOLs by attracting newcomers and putting an end to some existing collaborations.

### Dynamic management of selected KOLs

#### Current pool of selected KOLs
- Guidance for new product development
- Data generation (pre-clinical or clinical)
- Creation of credible and persuasive medical content
- Advice regarding product strategy (e.g. positioning)
- Facilitation of patient access to new therapies

#### Entering KOLs

- KOLs entering the reservoir of partners should fulfill specific objectives
- Depending on the needs to be fulfilled, the expertise and motives of the KOL, the expected engagement will be:
  - Either strategic and renewed for several years (partnership)
  - Or tactic and carried out on an ad-hoc basis (transaction) for a specific activity (e.g. lecture, clinical study)

#### Leaving KOLs

- KOLs may leave the reservoir of partners on the basis of:
  - Joint decision (e.g. completion of an ad-hoc agreement)
  - Decision made by the pharma company (e.g. engagement not satisfactorily fulfilled, difficulty to collaborate with the KOL)
  - Decision made by the KOL (e.g. mismanagement of the relationship by the company, lack of interest in the product or the requested activities)

---

Sources: Smart Pharma Consulting
Pharma companies should balance what they expect from KOLs in terms of activities and what they give them in terms of services to ensure a win-win partnership.

**Services proposed to & activities carried out by KOLs**

**Services proposed to KOLs (Illustrative)**
- KOL Digital Platform (2.0)
  - Access to scientific information (e.g. articles, databases, expert reports, clinical cases)
  - Technical support to publish articles (e.g. medical writing, proof reading, peer pre-review)
  - Slide kits for training/teaching programs
- Organization of peer meetings with top international KOLs (e.g. congresses, symposiums, forums, etc.)
- Technical & funding support for Investigator Initiated Studies
- Ad hoc support on demand basis (e.g. media training, training on statistics, change management in a ward)

**Activities carried out by KOLs (Illustrative)**
- Participation to scientific studies
- Advisory board member
- Article writing
- Lectures during symposia
- Promo material review
- Participation to internal meetings
- Press conference
- Training of peers / CME
- Training of peers / CME

**KOL Manager**

Sources: Smart Pharma Consulting

1 Access limited to KOLs – 2 Each KOL should have a dedicated KOL Manager (e.g. a MSL) – 3 Continuous Medical Education – 4 Such as lectures to sales forces, face-to-face meetings with the marketing team, etc. – 5 Such as visual aids, leaflets for patients
If KOLs share the objective of the pharma company and accept to communicate, the following means can influence medical practices and help better position products

**Potential value of KOL activities (1/2)**

- **KOLs may support the pharma company priorities by communicating in scientific journals, professional magazines or lay press regarding:**
  - New medical approaches, new guidelines, patient management, etc.
  - The position of its products in the therapeutic strategy

  - **Perceived reliability by readers:** H
  - **Number of exposed readers:** L-H

- **Press conferences enable to have indirectly access to a larger number of readers**
  - The messages conveyed by KOLs may sometimes be modified by journalists
  - It is rare for KOLs to make strong statements in favor of a product during a press conference

  - **Perceived reliability by readers:** M
  - **Number of exposed readers:** M-H

- **While giving lectures, KOLs may accept to cover topics of interest for the company**…
  - … and/or to position its product vs. direct competitors or indirect therapeutic alternatives based on scientific data/ rationale
  - KOLs may also share their own experience as a prescriber of the company products

  - **Perceived reliability by participants:** M
  - **Number of exposed attendants:** L

- **Press conferences enable to have indirectly access to a larger number of readers**
  - The messages conveyed by KOLs may sometimes be modified by journalists
  - It is rare for KOLs to make strong statements in favor of a product during a press conference

  - **Perceived reliability by readers:** M
  - **Number of exposed readers:** M-H

- **KOLs may communicate to HCPs during training sessions regarding:**
  - Medical topics of interest for the pharma company
  - The position of its products in the therapeutic strategy
  - In such circumstances, KOLs may convey strong messages, if they decide to do so

  - **Perceived reliability by participants:** M-H
  - **Number of exposed attendants:** M

_H: Higher – M: Medium – L: Lower_

Sources: Smart Pharma Consulting

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1. Continuous Medical Education  
2. Physicians, pharmacists, nurses, etc.
KOLs can be of great value through direct collaboration (by training, informing, giving advice, etc.) with medical and marketing teams of the pharma company

Potential value of KOL activities (2/2)

- **KOLs may play an effective role during internal meetings by:**
  - Informing / training medico-marketing teams about scientific trends and position of competitors
  - Being invited as a “guest star” to show collaborators the ability of the pharma company to partner with top medical leaders
  - Playing a role with sales reps (e.g. selling forums)

- **Advisory board meetings with KOLs should be preferred to individual meetings with KOLs when the objective is to get advice on:**
  - **Estimating** the impact of key market trends:
    - Scientific innovation
    - New product development
    - Evidence generation
    - Market access strategy
    - Marketing strategy (positioning)
  - New ideas or concepts

- **KOLs, especially if they are supposed to sign or co-sign the corresponding publication, may be very helpful to:**
  - Participate to the design of the study
  - Carry out the study (either about a given pathology only or a pathology & its treatments involving the pharmaceutical company product)

- **Involvement of KOLs in medical/clinical studies will depend on their field of interest**

- **KOLs may collaborate with the marketing team by contributing to the creation of promotional materials**
  - Thus, they can create value by:
    - Suggesting messages
    - Developing a scientific rationale to support messages/claims of the products
    - Assessing and editing the content of promotional materials (visual aid, booklet...)

Sources: Smart Pharma Consulting
A comprehensive KOL engagement strategy requires from pharma companies to gain an in-depth understanding of KOL challenges, motivators and expectations.

### Challenges
- **Trusting pharma**: product efficacy and safety, corporate reputation and service quality
- **Pharma engagement approach**: transactional arrangement vs. real relationship, multiple contact points
- **Time and doctor/patient ratio**
- **Regulation**: compliance, accountability, disclosure of compensation from pharma companies

### Motivators
- Prestige and renown
- Better healthcare outcomes
- Scientific journals and publications
- Membership in advisory boards, steering committees
- Formulation of guidelines and medical policies
- Speaking opportunities at congresses, symposia
- Participation in clinical trials and academic researches

### Expectations from pharma companies
- Fair market value remuneration
- Presence in KOLs field of expertise
- Consistency, communication, support and interaction
- Value-adding interactions with pharma companies collaborators
- Research assistance
- Credibility and commitment to patient care
- Continuous engagement
- Genuine involvement & meaningful partnerships
- Transparency

“One goal that most KOLs share is to capture attention and prestige within their community”
In general, the most common criticisms by KOLs at pharma companies are related to absence of true partnerships and of cohesive internal strategy and processes.

### Top 10 poor practices

1. “30-page confidentiality agreement”
2. Unclear unspoken objectives
3. Inconsistent honoraria payments across projects
4. Strong commercial bias in discussions about treatments
5. Lack of listening
6. Lack of on-going communication
7. Sporadic approach: “No follow-up to show how they used our input or what they did”
8. “17 different people from the same company contacted me in the course of one month”
9. Changes in staff: “I never know who is who”
10. Relationship held by the CRO

### Key learnings

- Set clear objectives
- Favor partnership-based to transactional agreements
- Consider what KOLs want from a relationship with pharma companies
- Ensure a transparent communication
- Have a clear demarcation between commercial, medical and clinical needs (and others, if needed)
- Ensure a consistent and coordinated communication between the pharma company and the KOLs

Sources: Study carried out in the UK, Uptake Strategies (January 2014) – Smart Pharma Consulting analyses
The development of a KOL Engagement Plan is a centerpiece to maximize the probability of success while partnering with KOLs

---

**KOL engagement plan (1/2)**

- The development of a clear – precise – concise and shared engagement (activity) plan, between KOLs and pharma companies – will ensure that:
  - Objectives of collaboration are well understood and agreed upon
  - Reciprocal expectations are well defined and accepted
  - Respective commitments are fulfilled and in due time

- The preparation of an engagement plan increases the probability of success of the partnership over time…

- … and minimizes the risks of mutual disappointments

- The KOL Engagement Plan (KEP) will facilitate the coordination and the communication across the pharma company and thus optimize synergies across market access, medical and marketing departments

---

Sources: Smart Pharma Consulting
To build a useful and effective KOL Engagement Plan, it is recommended to follow the 5-step process proposed here-below

1. Design of templates that can be shared with KOLs and the pharma company collaborators (i.e. from market access, medical, marketing departments)

2. Filling up of the plan by the pharma company collaborators assigned to the KOL under the supervision of the Medical Director and Marketing Director¹

3. Reviewing/adjustment of the plan by the KOL and the KOL Manager²:
   - Objectives
   - Services offered by the pharma company
   - Activities carried out by the KOL
   - Fees (if any) at a fair market value
   - Monitoring process of services/activities

4. Follow-up of the plan:
   - Prepare the planned services/activities
   - Analyze the quality of execution of these services/activities
   - Reconsider – if not anymore relevant – planned services/activities

5. Assessment of the engagement by:
   - The KOL Manager and the KOL to measure the level of mutual satisfaction and decide about potential adjustments³
   - A committee incl.: the Medical Director, the Marketing Director, the KOL Manager to evaluate the KOL engagement and decide about potential adjustments⁴

“*To find common ground is a key success factor in KOL engagement*”

Sources: Smart Pharma Consulting

¹ If allowed by national and corporate regulations – ² It is recommended to assign one KOL manager who is the preferred point-of-contact for the KOL – ³ Ideally, twice a year – ⁴ Ideally, once a year
Individual KOL Engagement Plans should be co-developed by the KOL and the pharma company to avoid any misunderstanding and subsequent disappointments.

### Development of KOL Engagement Plans

#### Strategic Brand Plan (2020 – 2023)

- The KOL engagement plan should be developed to support the Brand Strategic Objective as per the Strategic Brand Plan.
- Each individual KOL engagement plan should be designed accordingly and be consolidated in a single document.
- The Consolidated KOL Engagement Plan can cover a period lasting from one year to 3 or even 5 years, depending on the product position on its life cycle.

---

**Sources:** Smart Pharma Consulting
The KOL Engagement Plan should be formalized in a document that could be structured as proposed in the table of contents, here-below:

**Structure of a Consolidated KOL engagement plan**

<table>
<thead>
<tr>
<th>Table of Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Introduction</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>• Brand Strategic objective (vision)</td>
</tr>
<tr>
<td>• Brand Strategic Imperatives &amp; Critical Success Factors</td>
</tr>
<tr>
<td>• Brand development priorities (3-year perspective)</td>
</tr>
<tr>
<td><strong>Expected contribution from the pool of Global KOLs</strong></td>
</tr>
<tr>
<td><strong>Expected contribution from individual Global KOLs</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>• Type of agreement (ad-hoc, partnership, duration, etc.)</td>
</tr>
<tr>
<td>• Key activity selection (e.g. advisory board meeting, lecture, clinical study, peer-to-peer trainings)</td>
</tr>
<tr>
<td>• Key activity description (e.g. objective, timing, accountability, budget)</td>
</tr>
<tr>
<td>• Key activity monitoring (e.g. KPIs(^1) and KEIs(^2))</td>
</tr>
</tbody>
</table>

Sources: Smart Pharma Consulting

\(^1\) Key performance indicators – \(^2\) Key execution indicators
The KOL Engagement Plan should include key information extracted from the KOL database, specify the objectives of the collaboration, its scope and duration.

### Individual KOL engagement plan – ID Card

<table>
<thead>
<tr>
<th>KOL name</th>
<th>First name – surname</th>
<th>Medical status</th>
<th>Medical setting</th>
<th>Impact Index¹</th>
<th>Degree of Interest</th>
<th>Points of vigilance</th>
<th>Awareness</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expertise</td>
<td>E.g. therapeutic area, organ, pharmacology, academic and/or clinical research, scientific advisory boards, etc.</td>
<td>MD – head of medical department – professor of medicine, etc.</td>
<td>Private hospital – Public hospital – Teaching hospital</td>
<td>Publications – Lectures – Communication skills - Network</td>
<td>Low – Moderate – High</td>
<td>E.g. mobility, adherence to deadlines, quality of presentation documents, etc.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Primary objectives of the collaboration

- 

### Specific activities planned within the engagement¹

- 

### Type of agreement

- Transactional agreement:
- Partnership agreement:

### Duration of the agreement

- Annual: from: ---/---/--- to: ---/---/---
- Multi-year: from: ---/---/--- to: ---/---/---

Sources: Smart Pharma Consulting

1 Examples: Development of a digital tool to improve patients adherence, coordination of a multi-centric study, expert support to estimate the medico-economic value of a new product, lectures during medical meetings organized with peers, etc.
The KOL Engagement Plan should describe the activities the KOL is engaged to carry out to meet specific objectives, and it should include monitoring indicators.

### Individual KOL Engagement Plan – KOL Activity Card

<table>
<thead>
<tr>
<th>KOL Activity</th>
<th>Objectives</th>
<th>Pharma company contact point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lecture, training of peers, advisory board, press conference, article writing, IIS, clinical study, etc.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Key implementation steps</th>
<th>Timing</th>
<th>Points of caution</th>
<th>Expected output / value of the activity for…</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>... the KOL herself/himself</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Feasibility (High – Moderate – Low)</th>
<th>Key Execution Indicators</th>
<th>Key Performance Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical</td>
<td>• These indicators measure the quality of execution of the activity</td>
<td>• These indicators measure the impact (output/value/benefit) of the activity for the different targets (the KOL, the pharma company and possibly for 3rd parties, like peers, patients, PAGs)</td>
</tr>
<tr>
<td>Regulatory</td>
<td>•</td>
<td></td>
</tr>
<tr>
<td>Financial</td>
<td>•</td>
<td></td>
</tr>
</tbody>
</table>
The KOL Engagement Plan should also describe, plan and follow up the services proposed to the KOL, as a constituent of the partnership-based agreement signed.

### Individual KOL Engagement Plan – Partnership-based Service Card

<table>
<thead>
<tr>
<th>Key Implementation Steps</th>
<th>Timing</th>
<th>Points of Caution</th>
<th>Expected Output / Value of the Service for…</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>... the KOL herself/himself</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>... the pharma company</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Feasibility (High – Moderate – Low)</th>
<th>Key Execution Indicators</th>
<th>Key Performance Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical</td>
<td>•</td>
<td>• These indicators measure the quality of execution of the service provided to the KOL</td>
</tr>
<tr>
<td>Regulatory</td>
<td>•</td>
<td>• These indicators measure the impact of the service provided to the KOL</td>
</tr>
<tr>
<td>Financial</td>
<td>•</td>
<td></td>
</tr>
</tbody>
</table>
Key execution and performance indicators are essential to optimize the chance of a proper execution of services / activities and of a win-win partnership

4 Examples of tools to monitor engagements with KOLs (1/2)

<table>
<thead>
<tr>
<th>KOLs activities</th>
<th>Key execution indicators (KEIs)</th>
<th>Key performance indicators (KPIs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lecture during symposia or congresses</td>
<td>• Interest (10-point scale)</td>
<td>• Global level of satisfaction of attendees (10-point scale)</td>
</tr>
<tr>
<td></td>
<td>• Utility (10-point scale)</td>
<td>• Inclination of attendees to support &amp; prescribe the product:</td>
</tr>
<tr>
<td>Training of peers</td>
<td>• Practicality (10-point scale)</td>
<td>- Number of lectures/trainings/publications</td>
</tr>
<tr>
<td></td>
<td>• Implementation(^1) (10-point scale)</td>
<td>- Quality/objectivity of messages conveyed to peers, pharmacists, PAGs, etc.</td>
</tr>
<tr>
<td>Article writing</td>
<td>• Acceptance by recognized journals (scientific, medical, or in lay press, etc.)</td>
<td>• Impact factor and Altmetrics(^2) (for scientific / medical journals)</td>
</tr>
<tr>
<td></td>
<td>• Post on highly regarded websites</td>
<td>• Number of broadcasted issues for lay press</td>
</tr>
<tr>
<td>Press conference</td>
<td>• Number and quality of press conferences conducted</td>
<td>• Number of views / likes on Internet</td>
</tr>
<tr>
<td>Participation in scientific studies</td>
<td>• Implementation (number of patients recruited, timing, actual costs vs. budget)</td>
<td>• Contribution of content to support the product</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Publication of an article in a renowned scientific journal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Impact of the publication on product reputation</td>
</tr>
</tbody>
</table>

\(^1\) Logistics, timing, actual costs vs. budget – \(^2\) Collects and collates disparate information on the online activity surrounding scholarly content

Sources: Smart Pharma Consulting
Key execution and performance indicators are essential to optimize the chance of a proper execution of services / activities and of a win-win partnership

### Examples of tools to monitor engagements with KOLs (2/2)

<table>
<thead>
<tr>
<th>Pharma company services</th>
<th>Key execution indicators (KEIs)</th>
<th>Key performance indicators (KPIs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to scientific information</td>
<td>Interest (10-point scale)</td>
<td>Global level of satisfaction of KOLs (10-point scale)</td>
</tr>
<tr>
<td>Organization of peer meetings with top global / international KOLs</td>
<td>Utility (10-point scale)</td>
<td>Inclination of KOLs to support the pharma company products:</td>
</tr>
<tr>
<td>Publications support</td>
<td>Practicality (10-point scale)</td>
<td>– Number of lectures / trainings / publications</td>
</tr>
<tr>
<td>IIT(^1) support</td>
<td>Implementation(^2) (10-point scale)</td>
<td>– Quality/objectivity of messages conveyed to peers, pharmacists, patients, etc.</td>
</tr>
<tr>
<td>Slide kits for training / teaching programs</td>
<td></td>
<td>Increased level of KOLs awareness and reputation</td>
</tr>
<tr>
<td>Ad hoc support on demand basis</td>
<td></td>
<td>Increased level of products awareness and reputation</td>
</tr>
</tbody>
</table>

\(^1\) Investigator Initiated Trails – \(^2\) Logistics, timing, cost vs. plan

Sources: Smart Pharma Consulting
Future trends in KOL Engagement Planning

- Fewer opportunities for transactional and agreements (e.g. ad-hoc contributions such as lecture at a symposium)
- Greater independence of KOLs and increasing pro-bono contribution where mutual benefits lie (e.g. research program, lectures reinforcing their awareness)
- More independent collaboration projects, indirectly or not connected to a specific product (e.g. research program, education program, best practice sharing)
- Increasing presence, awareness and influence of KOLs on Internet
- Broader definition of KOLs from clinical expert to patient advocate, payor, academic institution, charity, etc.
- Evolving internal policies to foster transparency and compliance with industry code of practice

Sources: Study carried out in the UK, Uptake Strategies (January 2014) – Smart Pharma Consulting analyses
Recommendations for a Successful KOL Engagement Planning

1. Define **clear** and **precise objectives** for each KOL
2. Build a **relationship** based on an **exchange of services / activities** (vs. fee-for-service deal)
3. Make sure that **services** provided to KOLs **contribute to fulfill** their **needs/expectations**
4. Ensure an **open** and **transparent relationship**
5. Do not ask **KOLs** to **promote** your **products**, you would affect their reputation and yours
6. Make the **best use** of **KOLs limited time** by organizing useful exchanges
7. Assign a **KOL Manager** who is the KOL-preferred contact point and who ensures alignment and information sharing between all collaborators of your company in contact with her/him
8. Create a **technology platform** to **store, structure** and **share data** relative to KOL profiles and engagements (planned and achieved)

*Define internal guidelines and a control process to prevent any compliance issues that could damage your corporate reputation*
The Smart Manager Series (#4)

**Excellence in Execution ...**

- Key principles & Tools

... Applied to Pharma Companies

June 2019

“Excellence is not a skill. It is an attitude”

– Ralph Marston
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Sources: Smart Pharma Consulting
1. Introduction

Excellence in execution is essential to turn a strategy into a business success

- If the quality of R&D remains the primary success driver of innovative pharmaceutical companies, the quality of their medical, marketing and sales departments is also of utmost importance to turn new products into commercial successes.

- Actually, the great majority of drugs face strong competition, which requires the crafting of a solid medical, marketing and sales strategy to boost customer preference and hence optimize corporate revenues.

- However, business successes or failures are more dependent on the quality of the strategy execution than on the chosen strategy.

- The purpose of this position paper is to propose principles and practical recommendations to help pharma companies excel in executing their strategy.

"Strategy is about execution" – Sanjiv Anand

Sources: Smart Pharma Consulting
1. Introduction

Excellence, when applied to strategy execution, contributes to drive customer preference, optimize operational efficiency and corporate performance.

Strategy – Tactics – Execution – Excellence

- Strategies correspond to major mid- to long-term decisions
- Different strategies may enable a company to achieve its objective

<table>
<thead>
<tr>
<th>Strategy A</th>
<th>Strategy B</th>
<th>Strategy C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Execution</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Tactics encompass all activities that are executed to support the strategy
- Excellence is a spirit leading people to give their best

Priorities in marketing & sales excellence in execution consist in:
- Raising customer preference
- Optimizing operational efficiency
- Boosting corporate performance

Sources: Smart Pharma Consulting

1 Key Execution Indicators – 2 Key Performance Indicators
1. Introduction

The Smart Strategic Model helps to align the “Strategic Square” to the strategic objective and then to craft the best strategy and the corresponding tactics supported by the right organization.

The Smart Strategic Model™ – Principles

- **Purpose**: Why do we exist?
- **Vision**: What do we aspire to become?
- **Mission**: What do we do and for who?
- **Values**: What do we believe in and how do we behave?
- **Objective**: What do we want to achieve?
- **Strategy**: Where to play and how to play to win?
- **Organization**: What activities, processes, structure\(^1\) and culture we put in place to execute the strategy?
- **Key tactics**: How are we going to execute the strategy?
- **Performance**: What have we quantitatively and qualitatively\(^2\) achieved and what are the gaps and why, if any?

---

1 Including the headcounts and the organigram – 2 Such as corporate reputation (see our position paper on our website)
1. Introduction

The strategy should be crafted according to the analyzed situation and trends, and the strategic objective set, prior to the design/adjustment of the organization.

The Smart Strategic Model™ – Strategy & Organization

Situation & Trends Analysis

Competitive Landscape Analysis

Company Assets Assessment

Strategy Crafting

Strategic Objective

Organization Design

Marketing & sales strategies should be crafted to raise customer preference and create a long-lasting competitive advantage by:
- Seizing market opportunities
- Combating market threats
- Leveraging competitive strengths
- Addressing competitive weaknesses

The organization should be designed to support the crafted strategy efficiently. Four dimensions should be considered:
- Activities (and competencies)
- Structure (FTEs, organization chart)
- Processes (coordination, decision-making, information sharing, etc.)
- Culture (working conditions, etc.)

Sources: Smart Pharma Consulting
1. Introduction

Medical, Marketing & Sales departments must put into perspective the value drivers related to the three components of the Brand Preference Mix to gain/strengthen customer preference.

The Smart Strategic Model™ – Key Tactics (1/2)

- The 3 components of the Brand Preference Mix must be activated…
- … to bring superior benefits to customers than competitors do
- Marketing & Sales activities aim at promoting these benefits and convincing customers to recommend, buy or use the proposed products

Customer preference is driven by their:
- Needs: “I need a treatment for this disease that is effective and safe” [fact-based]
- Wants: “I want to prescribe this treatment because I feel more secure” [emotional]

But limited by their:
- Fears: “I am used to another treatment and do not wish to change my habits” [fact-based & emotional]

Sources: Smart Pharma Consulting
1. Introduction

Features of each pillar of the Brand Preference Mix should be expressed as benefits to customers in order to strengthen their preference to the brand

The Smart Strategic Model™ – Key Tactics (2/2)

<table>
<thead>
<tr>
<th>Brand Preference Mix (BPM)</th>
<th>Features of the BPM pillars</th>
<th>Benefits to customers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corporate reputation</td>
<td>• What to say and do to build an appealing image and establish the company as a reliable player?</td>
<td>The benefits the customers are likely to draw¹ should be identified for each feature of each component of the Brand Preference Mix</td>
</tr>
<tr>
<td></td>
<td>• How should these initiatives be carried out?</td>
<td></td>
</tr>
<tr>
<td>Brand attributes</td>
<td>• How to differentiate positively the brand from competition?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• How to highlight these attributes in an effective and efficient way?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• To whom these differentiating points should be communicated?</td>
<td></td>
</tr>
<tr>
<td>Service quality</td>
<td>• What services to develop to create a superior difference vs. competition?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• How to make sure these services are highly valued by customers? [Are they useful / interesting / convenient / well executed?]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• How should these services be executed to meet excellence?</td>
<td></td>
</tr>
</tbody>
</table>

Sources: Smart Pharma Consulting

¹ Benefits could be: functional, financial, emotional and/or self-expressive
1. Introduction

The Preference Ladder shows where do customers stand and how to make them move up to the ultimate preferential behavior step

The Smart Strategic Model™ – Expected Outcomes

- **Step 4**
  - Preferential behavior
  - **Leverage points**
    - Be highly desirable
    - Offer attractive experiences
    - Induce unmatchable perception of higher benefits

- **Step 3**
  - Preferential opinion
  - **Leverage points**
    - Offer higher benefits
    - Be significantly distinctive
    - Ensure superior execution

- **Step 2**
  - Positive opinion
  - **Leverage points**
    - Be relevant (what are the benefits?)
    - Be credible and legitimate
    - Ensure high quality of execution

- **Step 1**
  - Awareness
  - **Leverage points**
    - Communicate
    - Create experience
    - Stimulate / sustain memorization

To induce a preferential behavior in favor of their products, Marketing & Sales departments must make their customers climb the Preference Ladder.

While defining:
- **Activities** to be executed
- **Quality standards** of execution
- **Communication** priorities

It is key to monitor where each customer stands on the Preference Ladder and fine tune how to make them move up.

Sources: Smart Pharma Consulting
1. Introduction

Strategy and execution must be perfectly aligned to lead to success

Strategy and execution are closely intertwined since, to achieve an objective, it is necessary to choose:
- A strategy (approach) and
- The activities to be executed to implement that strategy

Case study: Starbucks

- Howard Schultz, former CEO of Starbucks, wanted his coffee shops to be the “third place” for conviviality beyond home and workplace
- Starbucks has managed to deliver its promise by:
  - Creating a warm layout and decor in its stores
  - The warm and friendly behavior of its employees who know how important they are to succeed

“Strategy without action is a daydream. Action without strategy is a nightmare”
2. Definitions

Excellence is a spirit leading people to give their best to beat competitors, to exceed customer expectations, in an efficient manner, to optimize corporate performance.

Excellence vs. Perfection

**EXCELLENCE**

- The pursuit of excellence is focused on the reason for a task and the results to make it a success.
- Excellence is related to:
  - Doing the right things (i.e. focus on what matters), making it more productive than perfectionism.
  - Looking for continuous improvement to deliver outstanding quality to outperform the competition.
- There is no fear attached to excellence.

**PERFECTION**

- If perfection is the ultimate goal, the business environment moves too fast to achieve it.
- Perfection is related to do things right.
- Looking for perfection is inefficient due to the inordinate amount of time required.
- Perfectionism has shown to cause anxiety and procrastination by fear of failure and thus to reduce people performance.

“Strive for excellence, not perfection”

Sources: Smart Pharma Consulting
3. Why is Excellence in Execution so Important?

Excellence in execution is the ability to carry out a plan in an outstanding and better manner than your competitors so that to generate customer preference.

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"The thing that keeps a business ahead of the competition is excellence in execution" – Tom Peters

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- If the right strategy is needed to achieve companies objectives, it is not sufficient.
- Actually, to produce its effect, the strategy must be well executed.
- Thus, looking for excellence in execution is imperative to create and increase the preference of customers.
- Execution excellence does not only boost sales, it also reduces costs by improving operational efficiency.
- According to John Kotter from Harvard Business School, 70% of strategies fail because of poor execution.
- Achieving excellence in execution is challenging because it requires to have the right tactics in place, the right capabilities and the right behaviors.

"When a strategy looks brilliant, it’s because of the quality of execution" – Rosabeth Moss Kanter

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Sources: Smart Pharma Consulting
# 4. Reasons for Poor Execution in the Pharma Industry

Poor medical, marketing and sales execution is mainly due to inadequate strategy, lack of customer insights, insufficient coordination and absence of efficient monitoring system.

## 10 factors preventing Excellence in Pharma Medical, Marketing & Sales Execution

<table>
<thead>
<tr>
<th>#1</th>
<th>#6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand strategy crafted at the global level is not necessarily relevant to local markets</td>
<td>Low enthusiasm from medical, marketing and sales teams who are insufficiently connected</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>#2</th>
<th>#7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unclear understanding of the brand strategy by medical, marketing and sales people</td>
<td>Activities carried out without prior evaluation of their likely impact on customers</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>#3</th>
<th>#8</th>
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<tbody>
<tr>
<td>Insufficient customer insights (knowledge and understanding of their wants and needs)</td>
<td>Non systematic evaluation of the impact of key activities on customer level of preference</td>
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<table>
<thead>
<tr>
<th>#4</th>
<th>#9</th>
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<tbody>
<tr>
<td>Poor quality of interactions with HCPs which are seen as useless and not interesting</td>
<td>Suboptimal collaboration and cooperation between medical, marketing and sales teams</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>#5</th>
<th>#10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inefficiency of first line managers to develop frontline collaborators competence¹</td>
<td>Lack of boldness from the regulatory department to accept innovative ideas</td>
</tr>
</tbody>
</table>

Sources: Smart Pharma Consulting

¹ Medical representatives, MSLs, KAMs, etc.
5. How to develop a Smart Execution Excellence Model?

Alignment on the objective, the selected strategy and the corresponding tactics, of collaborators involved in execution will make it more relevant and more efficient

Introduction (1/2)

- Make sure the selected strategy is accepted
- Make sure the situation analysis is understood
- Agree on most relevant tactics to support the strategy with those who will implement them
- Make sure the objective is shared and agreed upon
- Determine with the “implementers” the best manner to execute these activities in terms of efficacy, efficiency and motivation for them

<table>
<thead>
<tr>
<th>Execution</th>
<th>Tactics</th>
<th>Timing</th>
<th>Objectives</th>
<th>KEIs(^1)</th>
<th>KPIs(^2)</th>
</tr>
</thead>
<tbody>
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</table>

Sources: Smart Pharma Consulting

\(^1\) Key Execution Indicators – \(^2\) Key Performance Indicators
5. How to develop a Smart Execution Excellence Model?

Excellence in execution requires a participative and collaborative approach, to focus on the most important activities, to develop competence and to ignite passion of collaborators

Introduction (2/2)

- Involve employees in crafting the strategy to facilitate their buy-in, and make the execution both easier and smoother.
- Empower employees to develop their sense of ownership and figure out how best to meet the objective.
- Share values to make decisions aligned with the strategy.
- Ensure excellence in execution is focused on the most critical activities to achieve the strategic objective, which must be broken down in tactical objectives and thus in cross-team and/or individual objectives.
- Build plans which are practical (i.e. clear, concrete, familiar), flexible and adapted to market or company changes.
- Leaders must define the ways of working, how to exercise operational monitoring, inspire and mobilize the most talented employees.

A holistic approach to strategy and execution is required for a perfect alignment

- Set specific and measurable objectives to help frontline employees take ownership over their roles in the execution.
- Ensure that metrics measure that right things are done (KPIs) in the right way (KEIs).

- Involve employees in crafting the strategy to facilitate their buy-in, and make the execution both easier and smoother.
- Empower employees to develop their sense of ownership and figure out how best to meet the objective.
- Share values to make decisions aligned with the strategy.

Sources: Smart Pharma Consulting

1 Key Execution Indicators – 2 Key Performance Indicators
5. How to develop a Smart Execution Excellence Model?

Nine guiding principles to be applied and five key questions to be answered should help the implementation of a Smart Execution Excellence Model

Nine guiding principles

- Make it relevant
- Make it clear
- Make it ambitious
- Make it simple
- Make it participative
- Make it focused
- Make it rewarding
- Make it collaborative
- Make it exciting

Five key execution-related questions

1. What to do?
   Select the most relevant activities

2. Why to do it?
   Document the rationale to carry out these activities

3. How to do it?
   Define the best practices and the best organization

4. How well it has been done?
   Monitor the quality of execution

5. How close are we from the objective?
   Monitor the performance

Sources: Smart Pharma Consulting
5. How to develop a Smart Execution Excellence Model?

To achieve Excellence in Execution, companies must design an holistic organizational system that will foster the search for excellence by all its collaborators, front line and back-office ones.

Key organizational recommendations

- Develop a culture of superior customer satisfaction to gain customer preference and increase market share
- Develop a powerful vision so that people feel connected¹
- Install a participative culture²
- Engrain a culture of excellence
- Create a working atmosphere that will engage collaborators to give their best
- Encourage pro-activity, agility and experiment to find new solutions to excel in execution
- Facilitate and motivate cooperation and collaboration across multifunctional teams
- Develop enabling tools to:
  - Align objective, strategy and tactics
  - Measure the quality of execution and the impacts of activities
  - Reinforce the cohesion of the teams
  - Learn from experience
- Streamline processes and set up standards of excellence
- Define a process to facilitate participation of collaborators
- Provide direction and resources for achieving strategic objectives
- Focus on activities that best support the strategy and that the company excels at
- Carefully plan the execution of key activities and select a limited number of metrics to monitor the quality of execution and the impact of activities
- Develop the skills of managers and of their collaborators in charge of executing activities
- Design an adaptative structure that can be easily modified according to the changing environment
- Set up flat and lean organizational chart to favor accountability and empowerment
- Simplify structures by eliminating needless complexity
- Delineate lines of authorities and decision rights

Sources: Adapted from Scott A. Snell “In search of Execution” SHRM (2016) by Smart Pharma Consulting

¹ Set clear performance expectations, hold them accountable, give them regular feedbacks, reward their performance, share outcomes, etc.
² Solicit ideas and inputs, listen to people, select and implement their most appropriate suggestions
6. Case Study: The Mumbai Dabbawalas

The lunchbox delivery system carried out by dabbawalas is considered as one of the best-in-class model of service excellence in logistic for its level of accuracy and its timeliness.

Description of the Business Model (1/2)

- The dabbawalas deliver ~130,000 lunchboxes per day, in Mumbai area, from homes and restaurants to people at work.
- The lunchboxes are picked up in the morning, delivered predominantly using bicycles and railway trains by 1:00 pm.
- Lunchboxes are labeled using a system of signs, symbols, numbers, letters and colors indicating:
  - Where the lunch has been picked up
  - Which station it will be sent to
  - The final address of the owner
- This old-fashioned distribution system is more effective than Deliveroo or Uber Eats.
- It is recognized as one of the world’s most efficient logistics systems.
- The cost for the service is ~ €6 per month.
- The dabbawalas belong almost exclusively to the Varkari community, which worships the Hindu god Vithala who teaches that “giving food is a great virtue.”
- They are organized in a cooperative of 5,000 semiliterate partners, are self-employed and paid the same, around €190\(^1\) per month, and receive in addition tips from their customers.

Sources: Sources: “How Dabbawalas became the world’s best food delivery system” by Emma Henderson, Independent (2017) – Smart Pharma Consulting analysis.

\(^1\) Which is considered as a good salary in India, especially for unskilled labour.
6. Case Study: The Mumbai Dabbawalas

The low-tech distribution system carried out by the dabbawalas has been graded “Six Sigma”, meaning that the rate of mistakes is fewer than 3.4 per million transactions

Description of the Business Model* (2/2)

Collection at homes, in one single area from 8:30 to ~10:00 am

~30 lunchboxes collected per dabbawala, sorted and put onto a wooden crate according to the destination

40 seconds to load the crates with ~40 lunchboxes onto a train to the station closest to the destination

A single lunchbox goes through six dabbawalas before it reaches the consumer. The same rule applies for its return trip

Lunchboxes are sorted again, assigned to another worker who ensures the delivery by bicycle, cart or by foot

Delivery at work in one single area by 1:00 pm

Rate of errors: 1 per 16 million deliveries

Sources: “Mumbai’s models of service excellence” by Stefan Thomke, HBR (2012) – Smart Pharma Consulting analysis

* Description of the delivery system: https://www.youtube.com/watch?v=USb0eXtT2ys
6. Case Study: The Mumbai Dabbawalas

The efficacy of the dabbawalas distribution system is based on the perfect alignment of their organization, their management and culture which tend to reinforce one another

Analysis of the Business Model

<table>
<thead>
<tr>
<th>Activities</th>
<th>Structure</th>
<th>Process</th>
</tr>
</thead>
</table>
| Each dabbawalla is responsible for his allocated group of customers | 200 units of 20-25 groups of dabbawalas are headed by a supervisor | Simplicity is key
| Workers with more than 10-year experience serve as supervisors¹ | Flat structure ensuring agility | Each group is autonomous
| Tight schedule helps synchronize everyone and imposes discipline | 2 committees² tackle operational and organizational issues | 2-3 extra workers per group stand by in case of emergency

Process:
- Simplicity is key³
- Each group is autonomous
- 2-3 extra workers per group stand by in case of emergency
- Adherence to processes and to quality standards is mandatory
- Performance is based on schedule and proper lunchbox delivery

Culture:
- Dabbawalas remain in their group for their entire working life, which creates strong ties
- Most of them have the same culture
- They are proud to deliver food to people and have a strong sense of belonging

Dabbawalas mission: “Delivering food on time every time”

Sources: “Mumbai’s models of service excellence” by Stefan Thomke, HBR (2012) – Smart Pharma Consulting analysis

¹ There are 635 supervisors amongst the 5,000 dabbawalas – ² The Operational Committee and the Charitable Trust – ³ As shown by the coding system, the standardization of lunchboxes size and shape
7. Pharma Medico-Marketing & Sales Application

To get physicians to prefer a brand is becoming more complex, both in hospital and open care markets, due to increased price sensitivity and the multitude of influencers.

Situation analysis (1/2)

- Prescribing decisions are more and more made in concertation, following protocols, and through the influence and pressure of various stakeholders.
- The access to HCPs at hospital centers by Field Forces has become a burning issue.

- Office-based physicians prescribing behavior is more and more under the influence of health authorities, payers or other HCPs.
- Access to HCPs on the open care market segment has become a major issue for Field Forces.

Sources: Smart Pharma Consulting analysis
7. Pharma Medico-Marketing & Sales Application

Pharma companies must adopt an efficient organization to deal with bigger accounts, more and more price-sensitive, in which decision-making processes are complex

Situation analysis (2/2)

- Pharma companies have to address two key issues:
  - To protect, as much as possible, the price of their drugs
  - To move from a B-to-C to a B-to-B business model in which the prescribing decision is made by multiple stakeholders having different views and objectives

Sources: Smart Pharma Consulting analysis

1 Medical Science Liaisons – 2 Key Account Managers – 3 Key Institution Managers who are in contact with regional health authorities and payers and who can propose hospital centers to participate, for instance, to a local public health initiative on a given pathology – 4 Clinical Research Assistants
7. Pharma Medico-Marketing & Sales Application

Irrespective of the hospital key account, the strategy crafted by pharma companies should have a favorable impact on one or several of its four key performance drivers.

**Strategy Crafting on the Hospital Market**

- To boost their performance at hospital center level, pharma companies should activate one or several of the following key performance drivers:
  1. The listing on formularies
  2. The prescription for inpatients
  3. The prescription for discharged patients
  4. The prescription for outpatients

These drivers will be selected according to the objective set and the actions to activate them will depend on:

- Each hospital specificities (e.g. strategic priorities, procurement process and policy, degree of complexity, power games)
- Product portfolio competitive position
- Value of services offered to date
- Corporate reputation

Sources: Smart Pharma Consulting analysis

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¹ Through the therapeutic guidelines they may publish – ² Patient Advocacy Groups – ³ Under the direct responsibility of KAMs – ⁴ Under the direct responsibility of medical reps
7. Pharma Medico-Marketing & Sales Application

Field Force Teams operating on the open care market must secure access to customers and raise preference to their brand by ensuring highly valued interactions

Strategy Crafting on the Open care Market

- The expected outcome from customer strategy on the open care market is to:
  - Secure regular access to HCPs which is particularly difficult in health centers
  - Raise HCPs preference in favor of marketed products by leveraging the three components of the Brand Preference Mix
  - Maintain a favorable opinion and behavior of stakeholders who are likely to influence HCPs and patients

- To address these challenges, the Field Force Team members will have to:
  - Ensure highly valued interactions
  - Coordinate their activities to leverage potential synergies
  - Be flexible enough to adjust themselves to the external and internal changes

Sources: Smart Pharma Consulting analysis

¹ Through the therapeutic guidelines they may publish – ² Patient Advocacy Groups – ³ See Smart Pharma Consulting position paper “Best-in-Class Pharma Marketers” published in March 2017
7. Pharma Medico-Marketing & Sales Application

Field Force Teams activities should be regularly adjusted to secure a regular access to customers and boost their preference to the brands marketed by the company.

Organization – Key activities (1/2)

- Activities of Field Force Teams should be systematically streamlined:
  - Activities having no significant impact to raise the value of the marketed brands should be stopped
  - Customers shared by different Field Force functions (e.g. MSLs and medical reps) require a clear co-positioning to avoid duplication and a thoughtful coordination of activities to leverage potential synergies which will be driven by sharing competencies and/or costs

- To secure access to customers and influence them, Field Force Teams should, better than competitors:
  - Acquire a high level of market insights
  - Highlight the image of the company they work for
  - Propose and deliver highly valued services
  - Exhibit the benefits offered by the marketed brands
  - Use customer preferred communication channels

- Ambitious capability building programs would be required

Sources: Smart Pharma Consulting analysis

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1 Medical Science Liaison – 2 Key Account Managers – 3 Key Institution Managers – 4 Meaning: have an excellent knowledge and a good understanding of the healthcare system, the key market stakeholders (health authorities, competitors, customers) – 5 See Smart Pharma Consulting position paper “How to create a superior Pharma Corporate reputation” published in August 2016
7. Pharma Medico-Marketing & Sales Application

The development of Field Force Teams competencies can be structured and prioritized with the help of the Smart Index tool

Organization – Key activities (2/2)

- The **Smart Index** is a tool which structures the development of competencies around 3 components:

  \[ \text{Smart index} = \text{Knowing} \times \text{Understanding} \times \text{Behaving} \]

  **Knowing**
  - Precise, reliable & relevant knowledge of facts & figures re. the market, the company, with a special emphasis on customers and their influencers

  **Understanding**
  - In-depth & robust analytical skills and fact-based decision making

  **Behaving**
  - Planning, organizing, directing & monitoring to guarantee the quality of execution, leverage potential synergies and keep colleagues engaged

  “Any fool can know. The point is to understand” – Albert Einstein

Sources: Smart Pharma Consulting analysis
7. Pharma Medico-Marketing & Sales Application

High market sensitivity, simple and short processes, cross-departments coordination and cooperation will contribute to serve customers better

Organization – Processes (1/6)

- Customer-focused organization (silos around customers vs. brands)
- Knowledge- and experience-sharing
- Harmonization of activities

- Skills to develop and deliver high value solutions
- Ability to explore and discover customer insights (deep knowledge of their needs, wants, behaviors)
- Motivated and empowered collaborators

- Project teams including members from various departments centered around customers
- Shared customer database
- Introduction of metrics to foster cultural change

- Partnership with external players to propose unique and highly valued offerings to customers

Sources: Adapted from R. Gulati (HBR 2007) - Smart Pharma Consulting analyses
7. Pharma Medico-Marketing & Sales Application

To create value for field forces, and therefore for the company, head office functions should maintain a business-driven balance between support and control.

Organization – Processes (2/6)

- **Ad hoc** capabilities missing at Field Force level
- Complementary resources (e.g. if understaffing)
- Strategic directions and priorities, whenever required

- Support to facilitate in-field activities, to address scientific, legal, HR issues, etc.
- Competence and experience sharing across BUs and from head office to in-field functions

- Business-relevant metrics (automation, dashboards, standardized score cards)
- Selected number of KPIs (key performance indicators) and KEIs (key execution indicators)

- Monitoring of compliance (e.g. HR policy, people management, marketing & sales practices, etc.)
- Monitoring of the level of organizational agility and suggestions of solutions to fill up the gaps (if any)

Sources: Smart Pharma Consulting analyses
7. Pharma Medico-Marketing & Sales Application

The activities of in-field collaborators interacting with the same customers should be integrated in a single strategic plan, including separated sections

### Organization – Processes (3/6)

#### Medical Section
- **Collaborators:** MSLs
- **Key clients:** national and regional KOLs
- **Key objectives:** build strong and sustainable relationships with KOLs to develop advocacy
- **Key activities:** interactions with KOLs, scientific lectures at congresses, symposia, staff meetings, support of research clinical trials, training of speakers and collaborators from marketing and sales teams, support of Key Institution Managers (KIMs) and Key Account Managers (KAMs) while meeting their clients, competitive intelligence initiatives

#### Marketing & Sales Section
- **Collaborators:** brand managers, area managers, medical representatives
- **Key clients:** physicians, retail and hospital pharmacists
- **Key objectives:** strengthen brand preference
- **Key activities:**
  - **Marketers:** crafting of a brand preference strategy leveraging: brand attributes, perceived quality of associated services and corporate reputation
  - **Sales forces:** medical calls, invitations to medical meetings, congresses and proposal for services likely to strengthen brand preference

#### Access & Adherence Section
- **Collaborators:** Key Account Managers (KAMs) and Key Institution Managers (KIMs)
- **Key clients:** regional health authorities, regional payers, hospital directors, hospital purchase managers, PAGs
- **Key objectives:** facilitate the hospital listing, and improve patient adherence
- **Key activities:** development of medico-economic studies to facilitate the market access of brands and support of projects to improve patients adherence, to promote the proper use of drugs

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Sources: Smart Pharma Consulting analyses

1 Patient Advocacy Groups
7. Pharma Medico-Marketing & Sales Application

Four questions would need to be answered before deciding to implement any activity, which should then be monitored with KPIs and KEIs.

**Organization – Processes (4/6)**

<table>
<thead>
<tr>
<th>1</th>
<th>Calls to HCPs(^1)</th>
<th>Services to hospitals</th>
<th>Services to HCPs</th>
<th>Services to Patients(^2)</th>
<th>Mailings/E-mailings</th>
<th>Congress/symposium/meetings</th>
<th>Clinical studies</th>
<th>Publications</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>What is the objective of the activity?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>What is the activity target (nature and size)?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>How should the activity be implemented?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>What is the cost of the activity?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Selection of:**
- Key Performance Indicators (KPIs)
- Key Execution Indicators (KEIs)

*“What gets measured gets managed” – Peter Drucker*

---

Sources: Smart Pharma Consulting analyses

\(^1\) Carried out by Medical representatives, MSLs, KAMs, etc. – \(^2\) Through Patient Advocacy Groups (PAGs) or HCPs
7. Pharma Medico-Marketing & Sales Application

Before making the decision to invest in medico-marketing or sales operations, the expected impact should be clearly defined, as well as execution and performance indicators

Organization – Processes (5/6)

<table>
<thead>
<tr>
<th>What is the objective?</th>
<th>What is the target?</th>
<th>KEIs¹</th>
<th>KPIs²</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Create / reinforce awareness</td>
<td>▪ Physicians (e.g. KOLs, specialists, GPs)</td>
<td>% of the target covered by the Field Force Team</td>
<td>▪ Brand Preference Mix index (i.e. corporate reputation, product attributes, service quality)</td>
</tr>
<tr>
<td>▪ Generate interest</td>
<td>▪ Pharmacists (e.g. retail or hospital)</td>
<td>% of the target influenced by the Field Force Team</td>
<td>▪ % of hospitals having listed the brand</td>
</tr>
<tr>
<td>▪ Develop brand preference</td>
<td>▪ Patients</td>
<td>% of the target having a positive opinion of the services offered</td>
<td>▪ Price negotiation</td>
</tr>
<tr>
<td>▪ Increase share of prescription</td>
<td>▪ Nurses</td>
<td>Number of interactions (e.g. by customer, by in-field collaborator)</td>
<td>▪ Sales level and evolution</td>
</tr>
<tr>
<td>▪ Increase compliance</td>
<td>▪ Influencers (e.g. health authorities, “politics”, patient advocacy groups, public health insurance, private health insurance, professional associations)</td>
<td>Implementation time required vs. planned</td>
<td>▪ Share of prescription</td>
</tr>
<tr>
<td>▪ Limit substitution rate</td>
<td></td>
<td>Actual vs. budgeted cost</td>
<td>▪ Change in the number of treatment initiations</td>
</tr>
<tr>
<td>▪ Get the brand listed</td>
<td></td>
<td></td>
<td>▪ Return on investment</td>
</tr>
<tr>
<td>▪ Fine tune the profile of the customer</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


¹ Key Execution Indicators – ² Key Performance Indicators
7. Pharma Medico-Marketing & Sales Application

This type of tool is essential to prioritize and monitor the activities that are likely to contribute to reinforce the preference of customers for the brands.

Organization – Processes (6/6)

<table>
<thead>
<tr>
<th>Activity Description</th>
<th>Activity Objective</th>
<th>Target (HCPs, patients, etc.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key steps</td>
<td></td>
<td>Perceived benefit by the target</td>
</tr>
<tr>
<td>Description</td>
<td>Responsible</td>
<td>Timing</td>
</tr>
<tr>
<td>Description</td>
<td>Responsible</td>
<td>Timing</td>
</tr>
<tr>
<td>Key steps</td>
<td>Perceived benefit by the target</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Responsible</td>
<td>Timing</td>
</tr>
</tbody>
</table>

Barriers | Rationale | KPIs (Key performance indicators) | KEIs (Key execution indicators) | Expected Impact on Brand Preference Mix |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical L – M – H</td>
<td>Implementation</td>
<td>Indicate the metrics and the expected achievement</td>
<td>Indicate the metrics and the expected achievement</td>
<td>Brand</td>
</tr>
<tr>
<td>Regulatory L – M – H</td>
<td>Compliance</td>
<td></td>
<td></td>
<td>Service</td>
</tr>
<tr>
<td>Economic L – M – H</td>
<td>Estimated cost and return</td>
<td></td>
<td></td>
<td>Reputation</td>
</tr>
</tbody>
</table>

L: Low – M: Medium – H: High

Source: Smart Pharma Consulting

* 1 & 2 below competitors – 3 as competitors – 4 & 5 above competitors
7. Pharma Medico-Marketing & Sales Application

There is no magic numbers, the Field Force size depends on external and internal factors, the impacts of which are specific to each company and each product.

Organization – Structure (1/2)

Field Force sizing: Driving Factors

External factors

<table>
<thead>
<tr>
<th>Authorities</th>
<th>Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulations re. Field Force activities (charter)</td>
<td>Number of brands</td>
</tr>
<tr>
<td>Limitation of interactions with HCPs</td>
<td>Product life cycle stage (pre-launch, launch, growth, maturity, decline)</td>
</tr>
<tr>
<td>Refusal of institutions to interact with pharma companies</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Customers</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of HCPs and other customers (e.g. influencers such as PAGs, patients, payers)</td>
<td>Number of field days</td>
</tr>
<tr>
<td>Opinion and behavior vis-à-vis the company, its products and services</td>
<td>Type¹, content and frequency² of interactions</td>
</tr>
<tr>
<td>Inclination of customers to change their opinion and behavior under the influence of Field Force Teams</td>
<td>Number of daily interactions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Competition</th>
<th>Skills</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of targeted customers</td>
<td>Quality of contact</td>
</tr>
<tr>
<td>Type¹, content and frequency² of interactions</td>
<td>Contact productivity</td>
</tr>
<tr>
<td>Number of in-field FTEs</td>
<td>Territory management</td>
</tr>
</tbody>
</table>

Key factors to estimate Field Force size

¹ Including: face-to-face calls, mailings and e-mailings, contacts during medical meetings, congresses, project collaborations, etc.
² Per targeted customer

7. Pharma Medico-Marketing & Sales Application

The preferred structure should be built around customers, remain lean and agile to favor collaborations across departments and with the support functions.

Organization – Structure (2/2)

- In the **Product-focused model**, products drive the structure:
  - For “strict” hospital use, activities are organized in BUs or franchises, gathered or not under a common “Hospital Management” structure, and covering different therapeutic areas (TAs).
  - For mix products, companies display hospital dedicated med reps, reporting to open care BUs, and supporting detailing of open care products at hospital.
  - Hospital and open care organizations are operationally independent, but share common supporting resources.

- The **Customer-focused model** is shaped around customers by franchise, each of them containing marketing and medical resources, supported by sales forces.

- The **Functional model** is less frequent among pharma companies, irrespective of their size.

**Typical structure of pharmaceutical companies**

- **Product-focused model**
  - Hospital BU
  - Open care BU
  - Marketing
  - Sales

- **Customer-focused model**
  - Customer type 1 Franchise
  - Customer type 2 Franchise
  - Franchise
  - Medical
  - Marketing

- **Functional model**
  - Marketing
  - Sales
  - TA 1
  - TA 2
  - Line A
  - Line B

**Source:** Smart Pharma Consulting benchmark study
7. Pharma Medico-Marketing & Sales Application

Employees should be managed dynamically, by attracting best performers, developing and making them feel strongly engaged, while granting them the level of autonomy they deserve

Culture (1/3)

- Recruit gifted people
- Highlight the mutual benefits expected from collaboration

- Give them a sense of purpose
- Develop & motivate them
- Grant autonomy based on ability

- Do not keep those who under-perform
- Make sure all departures occur in a fair and nice way

“Alone we go faster, together we go further” – African proverb

Source: Smart Pharma Consulting benchmark study
7. Pharma Medico-Marketing & Sales Application

Stimulating Field Force members passion for their job is a key performance driver, especially in a context where customers are increasingly reluctant to meet them.

Source: Smart Pharma Consulting benchmark study

Culture (2/3)

Job passion is influenced by six key drivers:
- Sense of Purpose
- Achievement
- Recognition
- Challenges
- Rewards
- Autonomy

Passion is expressed by:
- Satisfaction
- Motivation
- Enthusiasm

Leading to
- Consistently More & Better Work

"Pleasure in the job puts perfection in the work" – Aristotle
7. Pharma Medico-Marketing & Sales Application

Managing by mutual benefits will give people a sense of purpose which will increase the probability to get their full and sustainable engagement

Culture (3/3)

<table>
<thead>
<tr>
<th>MBO² (Management By Objectives)</th>
<th>MBMB (Management By Mutual Benefits)</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Definition of objectives agreed by both management and employees</td>
<td>▪ Creates mutual benefits and value by fulfilling the respective expectations of employees and employers</td>
</tr>
<tr>
<td>▪ Well-adapted to vertical management models</td>
<td>▪ Maximize the probability to obtain the full engagement of employees</td>
</tr>
<tr>
<td>▪ However, by focusing on results, the way to achieve them (the planning) can be overlooked and lead to suboptimal efficiency</td>
<td>▪ Requires from managers to (better) satisfy collaborators …</td>
</tr>
<tr>
<td>▪ Does not favor innovation nor flexibility</td>
<td>▪ … to create favorable conditions to secure a higher quality of execution that will lead to better results</td>
</tr>
</tbody>
</table>

Source: Smart Pharma Consulting benchmark study

¹ The term was coined by Peter Drucker in 1954 in the book “The practice of Management”
8. Conclusion

Excellence in Execution requires to set a shared objective, the relevant strategy to reach it and high standards of quality, and to ignite the passion of collaborators

6 Tips to boost Excellence in Execution

1. Set the **ambition** of delivering **product** and **service excellence** to customers, which are second to none

2. The **strategy** set should be **explained** to align, inspire and **motivate** people in charge of its execution to excel

3. The **structure** and **processes** should **facilitate** / **encourage** the search for **excellence** by all the collaborators of the company

4. The **team** in charge of execution should be **capable**, **accountable** and **passionate** about exceeding customer expectations

5. The **executed activities** should be **focused** on the **actions** the company excel at and that are the **most important** to support the strategy

6. The **activities** supporting the strategy should be **carefully planned** and **monitored** with execution and performance indicators

“Excellence is a set of beliefs, ways of thinking, a matter of discipline, and ways of focusing”

Sources: Smart Pharma Consulting
8. Conclusion

If you have ticked seven “Yes” boxes or more, you are on the right track to move closer to Excellence in Execution, but keep in mind that excellence is a moving target.

Where do you stand on the Excellence in Execution Scale?

1. You have a clear **understanding** of the Purpose – Vision – Mission – Values of the company and you **share** it
2. The medical, marketing and sales **objectives are achievable** and the crafted **strategy is appropriate**
3. The **organization** is particularly **well-designed** to implement the strategy through your activities
4. You have the **right means** (human and financial resources) to implement the strategy
5. You have the **right skills** to meet customers **expectations** and **raise** their **perceived value** of your products
6. You know how to **conduct projects** in an effective and efficient way
7. You have built a **good reputation** with your customers
8. You are **passionate** about your job
9. You regularly **measure** the **quality of execution** and the **impact of your actions**
10. Your feel highly **satisfied** and **proud** when you manage to **excel in the execution** of an activity

Sources: Smart Pharma Consulting
9. Training program – Intra-company

How to apply the principles of Excellence in Execution?

Content & Organization

- The program will include basic definitions, recommendations, key tools, practical exercises and case studies relative to the pharmaceutical industry.
- The program content will be customized according to the specific needs of the clients.
- The program duration will be of one day, one day and a half or two days, according to the client needs.

Example of a One-Day Program

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:00</td>
<td>Introduction to the program</td>
</tr>
<tr>
<td>9:10</td>
<td>Review definitions and basic principles related to Excellence in Execution, in general and in the context of the pharma business</td>
</tr>
<tr>
<td>10:40</td>
<td>Break</td>
</tr>
<tr>
<td>11:00</td>
<td>Exercises: Setting strategic objectives – Crafting a strategy – Selecting and executing supporting activities – Designing the appropriate organization</td>
</tr>
<tr>
<td>12:30</td>
<td>Lunch</td>
</tr>
<tr>
<td>13:30</td>
<td>Case study #1: Practical implementation</td>
</tr>
<tr>
<td>15:00</td>
<td>Break</td>
</tr>
<tr>
<td>15:20</td>
<td>Case study #2: Practical implementation</td>
</tr>
<tr>
<td>16:50</td>
<td>Conclusion and key takeaways</td>
</tr>
<tr>
<td>17:30</td>
<td>End of the program</td>
</tr>
</tbody>
</table>

Target Audience

- Any collaborators from pharmaceutical companies, whatever their level of responsibility and seniority.
- Participants can be part of the medical, marketing, commercial, market research, strategic,… departments.

Sources: Smart Pharma Consulting
The Smart Manager Series (#5)

Storytelling in Business

Key principles & Tools

Survival Kit

June 2019

“The most powerful person in the world is the storyteller”

– Steve Jobs
1. Introduction

Storytelling is a unique tool to communicate a message, it captures attention and engages the mind through emotions

- The purpose of business storytelling is to help improve credibility and engagement to an organization through the sharing of a well-constructed speech

- The aim of this position paper is to understand the power of storytelling as a tool in business and to provide the key practices to best implement it in organizations

“We want to hear information through stories, with villains, characters, and a hero to rally around. It’s the way the world and our brains work. We’re wired that way” – Carmine Gallo

“Marketing is no longer about the stuff that you make, but about the stories you tell” – Seth Godin

Sources: Smart Pharma Consulting
What is storytelling?

Storytelling is a very old technique which is considered as one of the most effective and influential means to reach people and move them with a message.

Storytelling consists in sharing stories through different media to disclose the narrative of a story.

- A story describes what happened
- A good story helps you see what happened
- A great story helps you feel what happened

The 4 Cs of a story

To create a great story, 4 components are required:

- The Context which indicates when and where the story happened
- The Characters to create connections and emotion with the audience
- The Conflict which drives the action of the story, creates tension and that is likely to be resolved at the end of the story
- The Creation which defines the telling, the way the context, characters and conflict are articulated into a narrative

“A story is a fact wrapped in context and delivered with emotion” – Indranil Chakraborty

Storytelling & modes of persuasion

The Aristotle’s modes of persuasion, based on the ethos, logos and pathos triad build credibility, stir emotions and prompt action

Aristotle has written “The Art of Rhetoric”, more than 2,000 years ago in which he proposed three modes of persuasion:

- **Ethos** (credibility) of the storyteller which depends on his:
  - Good sense
  - Good moral character
  - Goodwill

- **Pathos** (emotion) which is used to build a common bond with the audience through a shared identity and/or shared values, and inspire action by stirring emotions such as:
  - Anger and Calmness
  - Fear and Confidence
  - Kindness and Unkindness
  - Envy and Emulation

- **Logos** (logical argument) is based on:
  - Deductive reasoning (e.g. syllogism¹)
  - Inductive reasoning (from specific to general²)

and is important to demonstrate strong evidence with the help of facts, figures and testimony to support conclusions

Sources: Adapted from “Know the three modes of persuasion”, Jeremy Porter (2014) by Smart Pharma Consulting analyses

¹ “All humans die (premise) – You are human (premise) – You will die (conclusion)” 
² You used to commute by car (premise) – Tomorrow you have to commute (premise) – You will probably commute again by car (conclusion)
Neurobiological findings on storytelling have shown that character-driven stories with emotional content are more persuasive and memorable.

Storytelling evokes strong neurological responses:

- The stress hormone cortisol is produced by our brain during the tense moments in a story, which helps the audience to focus.
- The oxytocin (the “feel-good” chemical) is produced when we are trusted or shown kindness, and it motivates cooperation with others.
- A happy ending to a story triggers the limbic system – our brain’s reward center – to release dopamine which makes us feel more hopeful and optimistic.
- Character-driven stories cause increased oxytocin synthesis which motivates people to engage in cooperative behaviors.
- Studies have shown that, in order to motivate a desire to help others, a story must first sustain attention by developing tension during the narrative.

Why use storytelling? (1/2)

It has been shown that storytelling makes facts and figures delivered with emotion more convincing and memorable, and thus more persuasive

- Storytelling is deeply rooted in making an emotional connection with another person
- The neuroscientist Antonio Damasio has shown that emotions play a central role in decision-making
- The British Institute of Practitioners in Advertising (IPA), analyzed the impact of 1,400 marketing campaigns on profit gains and demonstrated that, when based on…:
  - … logic, they are 16% effective
  - … emotion, they are 31% effective
  - … logic and emotion, they are 26% effective
- Stanford Marketing Professor Jennifer Aaker has shown that stories are remembered up to 22 times more than facts and figures alone

- Millennials¹ (or Generation Y) and Generation Z² base their relationships with brands on emotional attachments with stand-out companies
- People are more and more keen to give a sense to what they do
- Storytellers can engage audiences deeply with the right balance of emotion and key facts

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“To win a man to your cause, you must first reach his heart” – Abraham Lincoln

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Sources: Smart Pharma Consulting analyses

¹ Demographic cohort of people who were born between early 1980s and mid-1990s – ² Demographic cohort after the Millennials, using the mid-1990s to the mid-2000s as starting birth year
Why use storytelling? (2/2)

Storytelling can be used to shape vision, to pass on knowledge and wisdom and to shape identity and organizational culture

- A story creates an emotional experience that the audience will remember

- Some brands (e.g. Apple, Coca-Cola, Virgin, etc.) trigger an emotional feeling – positive or negative

- These brands, like many others, have a personality

- This personality, generating emotions, differentiates a brand from a product

- The critical aspect of stories is the feeling they create; so one must relate to stories associated to the brands and not to its commercial elements

- The corporate narrative provides the framework for getting everyone on the same page

- Stories can help — internal and external — audiences understand the value of a product, a company, a decision

- A clear narrative helps employees appreciate the vision of where the company is headed and empowers them to use their own creativity to get there

- Corporate story and storytelling help leaders to communicate their vision to their community

- A powerful way to persuade people is by insinuating an idea with an emotion

- A compelling story combines information and actions to stimulate emotion and energy

“90% of human behavior and decision-making is driven by our emotions” – Christine Comaford

Sources: Smart Pharma Consulting analyses
Telling the right story: Seven narrative patterns

Telling the right story will provide meaning and evoke a sense of purpose while helping the audience relate, empathize and remember

- **To spark action**
  - Describe, straight to the point, how a successful change was implemented in a way the audience imagines how it might work for them

- **To tell who you are**
  - Tell who you are, what you have done, what you think, based on a life event that reveals some of your strengths or weaknesses from your past

- **To transmit values**
  - Use characters – real or fictional – in a situation that will prompt discussion about the issues related to the value being promoted

- **To foster collaboration**
  - Tell a story that collaborators have also experienced and that prompts them to share their own stories, and have a plan ready to tap the energy released

- **To communicate on brands**
  - The story should relate to products, services or companies and reflect the brand promise as it is delivered and perceived

- **To share knowledge**
  - Focus on mistakes made and show how they were corrected, with an explanation of the reasons why the solution worked, and solicit other solutions

- **To lead into the future**
  - Evoke the future you want to create without providing excessive details that will only turn out to be wrong

---

Business storytelling tips

The 5 following essential tips will guide the preparation and delivery of business storytelling likely to be successful

1. Know the audience
2. Define the right message
3. Be authentic
4. Keep it simple & visual
5. Involve the audience

1. Know the audience

The stories should be crafted according to the audience perspective, and thus the same story should be adapted accordingly

- You must know your audience:
  - What are the audience experiences and expertise?
  - What are their thoughts and concerns?
  - What are their needs and wants?
  - What do they expect from you?
  - What would resonate well to them?

- Thus, to tell the right story, it is essential to know what the audience values and what the audience is likely to be interested by to create empathy and craft a story which is relatable

“Make sure you find common ground with people to whom you are telling stories” – Nancy Duarte

Sources: Smart Pharma Consulting
2. Define the right message

The message that will be conveyed should serve the objective of the storytelling and in a form that will generate emotion and empathy

- Define the idea you want to communicate according to your intent (e.g. the action you want the audience to take, the feeling you want them to have, the opinion you want them to modify)

- The way you will communicate your message should be related to the audience on a human level

- Do not just share information, … tell a story:

  **Information sharing**
  “Smart Pharma has helped more than 80 companies addressing strategic, management and organizational issues”

  Likely to be perceived as boring and not different from competition

  **Storytelling**
  “Imagine your smartphone breaks down. Don’t worry because at Smart Pharma we deliver services 24/7 to solve your problems”

  By using metaphors and anecdotes, it is possible to tell compelling stories

“People will forget what you said and did but will remember how you made them feel” – Maya Angelou

Sources: Smart Pharma Consulting
3. Be authentic

Authenticity is key to gaining audience trust and creates an emotional connection, without fear, to show your own challenges and failures

- Ideally, storytelling should not be fictional because a genuine narrative is more likely to connect with the audience

- If the audience can relate to a real-life story, you are making a connection and building trust

- Anecdotes that illustrate overcoming struggle, failures and barriers are what makes the teller appear authentic

- Storytelling is an effective way to communicate if you actually mean what you’re saying

- The key is to show some vulnerability

- Be you, just you! Don’t pretend to be anyone else

- If your stories are honest and transparent, you can win over your audience

- Storytelling brings more authenticity into business…

- … which explains why blogs and social media recommendations are so relied on and impactful

“The stories that move and captivate people are true to the teller and the audience” – Peter Guber

4. Keep it simple and visual

Most of the successful and memorable stories are relatively simple, straightforward and can be enhanced by a limited number of well-chosen visuals.

- Apply the KISS principle: "Keep It Simple, Stupid"
- Messages should be clear, precise and concise, without focusing on the details
- Simplicity is a challenge when subjects are complex
- The number of substantive arguments and persuasion principles should be limited

- Visual storytelling (e.g. animated images, videos) allows complex data to be broken down into smaller digestible pieces and chunks of memorable information
- Visual aids help improve engagement and retention
- Visuals are the most effective communication vehicles for evoking emotion and getting people to take action

Visuals drive emotions
Emotions drive decisions
Decisions lead to action

5. Involve the audience

Stories must be built and delivered so that the audience can feel involved as being a character of the story

- We cannot tell a story if we don’t feel that there is someone listening to us and paying attention

- Storytelling is about connecting

- You need to be vulnerable and connect to the vulnerability of others

- We can’t really listen to a story when the storyteller is not aware of his or her audience and is instead caught up in his or her own speech bubble

- In this most basic sense, there is a reciprocal relationship between listening and telling

- People like to be a part of stories

- Your audience can be characters in your stories

- Come up with ways to get your audience involved

- Get your audience involved in the presentation:
  - Ask questions
  - Brainstorm
  - Challenge them

“A good storyteller makes the target audience part of the story he tells”

Sources: Smart Pharma Consulting analyses
Structuring the story – Freitag’s Pyramid (1/2)

Freitag’s pyramid uses a 5-part system to describe the story plot, the climax being the high point which is surrounded by rising and falling actions.

To capture attention, convey emotion and engage the audience, stories need a dramatic arc, some conflicts to arise and after the struggle, a resolution.

1. Exposition (Inciting moment)
2. Complication (Rising action)
3. Climax (Turning point)
4. Reversal (Falling action)
5. Denouement (Moment of release)

“A story without a challenge, simply isn’t interesting” – Caroline O’Hara


1 Gustav Freytag was a 19th century German novelist who saw common patterns in the plots of stories and novels and developed a diagram to analyze them – 2 Sequence of events through the principle of cause and effect
Structuring the story – Freitag’s Pyramid (2/2)

Structuring stories by using Freitag’s Pyramid will help to raise audience attention and forge an emotional connection likely to change their opinion and behavior

3. Climax

- It is the most intense moment (either mentally or in action) or the greatest tension in the story, turning positively for the protagonist in a comedy or negatively in a tragedy

- A single event usually signals the beginning of the main conflict, rising tension

- The story builds as sequential events happen and…

- … becomes more exciting with a series of conflicts and crisis

2. Complication

1. Exposition

- This 1st step marks the start of the story where the scene is set (time and place)

- The teller introduces the characters providing description of the situation and establishing the atmosphere of the story

4. Reversal

5. Denouement

- It is the event that occurs as a result of the climax, and marks up the story will end soon

- At this point, any secrets, questions or mysteries which remain after the resolution are solved by the characters or explained by the teller

Note: As an example of the implementation of the Freitag's Pyramid, see the TED show presentation of Richard Tuere: https://www.ted.com/talks/richard_tuere_a_peace_treaty_with_the_lions/up-next?language=fr


1 Protagonist, hero, antagonist
How to compose a story: Practical recommendations

To grab attention of the audience and make a story relatable, engaging and compelling, the story should be structured according to the classic narrative arc

1. Who is my audience?

- Know your audience to craft a story that has a meaning for them

2. What is the message I want to share?

- Why are you telling the story?
- What do you want the audience to think, feel or do at the end of the story?

3. What is the story I want to tell?

- Tell a story that has a meaning for you
- Tell a story that actually happened
- Pick a story that addresses a problem the audience has

4. How I structure my story?

- Pick a main character similar to the audience
- Start your story with some context
- Something must be at stake
- Have a happy or constructive ending from which lessons can be learned

Sources: “Storytelling and other strategies in the art of persuasion”, Bill Chiat – Jennifer Aaker – Smart Pharma Consulting

1 As per the Freytag’s pyramid – 2 Place, date, etc.
How to deliver a story: Practical recommendations

The delivery of the story being as important as its composition, it is essential for the storyteller to be well-prepared and to practice

1. Style
   - Talk in a relaxed and direct way
   - Keep stories focused and simple
   - Be yourself
   - Be confident (no apologies)

2. Truth
   - Tell the truth as you see it
   - Be cautious while disclosing information about other people
   - Be congruent

3. Preparation
   - Rehearse, but don’t lose your spontaneity
   - Stick to the structure of your story
   - Test your story on others to check if you changed their perspective

4. Delivery
   - Be lively (use body language, voice inflection, make pauses)
   - Connect with the audience
   - Use pauses for emphasis
   - Keep it short (~6 to 8 minutes)

Sources: “Storytelling and other strategies in the art of persuasion”, Bill Chiat – Smart Pharma Consulting
The Apple case

Steve Jobs was not a natural speaker but used to work really hard, rehearsing again and again to make keynote presentations look effortless and conversational.

- Steve Jobs introduction of the first iPhone in 2007 was a masterpiece
- Then, even as the audience is starting to catch on, he lingers in the suspense a bit longer before making the reveal: a three-in-one mobile phone that would change the world forever
- Jobs was building the iPhone brand even before the audience had seen it, and the story was consistent with the company brand Apple had already built
- Apple knew they had made something exceptional
- Today, Apple continues Steve Jobs tradition of storytelling
- They do a great job of telling a story about what it looks like for customers to successfully use their products
- Apple weaves their products seamlessly into the story
- They also show how their products help people create their own stories, and Apple highlights the stories people create

What can we learn from Apple?

1. **Hook the audience** first, introduce your product second
2. **Build suspense**
3. **Focus your story on customers** successfully using your product

Sources: “How Airbnb & Apple build their brands with storytelling marketing”, Jarom McDonald (February 2016) – Smart Pharma Consulting

https://www.youtube.com/watch?v=z9w6tO4d90U
The Airbnb case

Airbnb has built its brand with storytelling marketing, focusing on people, telling stories about people, Airbnb hosts from around the world, thus creating connection.

- Airbnb content is focused on the people who own the homes listed and the travellers who go there.
- They show how connecting with others is important to their brand and how their brand makes that possible.
- It is a very human approach with a clear statement about the importance of stories to the Airbnb brand.
- There is an entire page on their website labelled airbnb.com/stories with videos and biographies of hosts around the world.
- Airbnb is also experimenting, on their website, a brand magazine called Pineapple which is “a platform for incredible stories from Airbnb family to be shared; showing how people live and create connections in cities today.”
- This meshes perfectly with Airbnb approach which focuses on stories and people, which is the language by which humans communicate; this approach attracting more customers.

Sources: “How Airbnb & Apple build their brands with storytelling marketing”.
Jarom McDonald (February 2016) – Smart Pharma Consulting

What can we learn from Airbnb?
1. Always seek connection between the brand and the audience.
2. Always bring it back to the human element.
3. Be sincere.
Key learnings

Storytelling can help companies connect with their audience and build a long-lasting relationship of loyalty with their customers and increase employee motivation

- As an emotional tool, storytelling creates purpose and drives action from the audience
- Well-constructed storytelling is an effective tool to inspire, engage and motivate your team
- Through imagination, stories help customers visualize the context of a company, its challenges and comprehend its strategy
- Many companies use storytelling to tell their story, share their values and aspirations and create a lasting bond with their target audience
- In order to craft an impactful story to tell, an analysis of the targeted audience is required to understand its concerns, perceptions, personalities and priorities
- A great crafted story is not sufficient to move an audience, its delivery through a plotted speech is necessary to achieve a behavioral change
- Telling a great story can help to leverage the full potential of a brand and to distinguish from competition

“Stories evoke emotion and inspire action”

Sources: Smart Pharma Consulting
6. Training program – Intra-company

One-day program to define relevant storytelling

Content & Organization

- The program will include basic definitions, recommendations, key tools, practical exercises and case studies related to the pharmaceutical industry.
- The program content will be customized according to the specific needs of the client.
- The program duration will be of one day, one day and a half or two days, according to the client needs and desire.

Example of a One-Day Program

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:00</td>
<td>Introduction to the program</td>
</tr>
<tr>
<td>9:10</td>
<td>Review definitions and basic principles related to storytelling, in general and in the context of the pharma business</td>
</tr>
<tr>
<td>10:40</td>
<td>Break</td>
</tr>
<tr>
<td>11:00</td>
<td>Exercises: Know your audience – Define the right message – Be authentic – Keep it simple &amp; visual – Involve the audience</td>
</tr>
<tr>
<td>12:30</td>
<td>Lunch</td>
</tr>
<tr>
<td>13:30</td>
<td>Case study #1: Practical implementation</td>
</tr>
<tr>
<td>15:00</td>
<td>Break</td>
</tr>
<tr>
<td>15:20</td>
<td>Case study #2: Practical implementation</td>
</tr>
<tr>
<td>16:50</td>
<td>Conclusion and key takeaways</td>
</tr>
<tr>
<td>17:30</td>
<td>End of the program</td>
</tr>
</tbody>
</table>

Target Audience

- Any collaborators from pharmaceutical companies, whatever their level of responsibility and seniority.
- Participants can be part of the medical, marketing, commercial, market research, strategic,… departments.

Sources: Smart Pharma Consulting
“Storytelling is the most effective way to combine meaning & emotions”
The Smart Pharma Publications

- Our publications have in common to:
  - Be well-documented and propose in-depth analyses
  - Share innovative concepts, methods and tools

Smart Pharma 2019
Half-Year Publications

- This e-book is the collection of our publications from January to June 2019
- Thus, we have published seven new position papers:
  - Market Insight & Strategy
    - Pharma Market Insight Studies
    - The French Pharma Market 2018 – 2023 Prospects
    - Succeeding on the French Biosimilars Market
  - Management
    - Hospital & Institution Relationships in Regions
    - Strategic KOL Engagement Planning
    - Excellence in Execution
    - Storytelling in Business

Smart Pharma Consulting Editions

- Besides our consulting activities which take 85% of our time, we are engaged in sharing our knowledge and thoughts through our:
  - Publication of articles, booklets, books and business reports
  - Teaching and training activities

Smart Pharma Consulting has published:
- 17 business reports regarding:
  - The French healthcare system and pharma market
  - The French generics and biosimilar markets
  - The French pharma distribution
  - The French OTC market
  - The market access and drug valuation
  - The global biosimilars drugs market
  - The best performing pharma companies
  - The pharma digital marketing
- 42 articles dedicated to pharma business issues
- 66 position papers since 2012

Best regards,
Jean-Michel Peny