

# The Best of Smart Pharma 2017

Concepts

Methods

Tools



**Smart Pharma**  
**Consulting**

## 1. **Business Reports** (Excerpts)

- French Pharma Market
- French Generics Market

## 2. **Smart Manager Series**

- Be a Smart Manager
- Time Optimization

## 3. **Best-in-class Series**

- Medical Science Liaisons
- Pharma Marketers
- Medical Reps
- Hospital KAMs
- Pharma BD&L

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***“Becoming Smarter is our ambition – Delivering Smarter Services our mission –  
Being Innovative our obsession”***

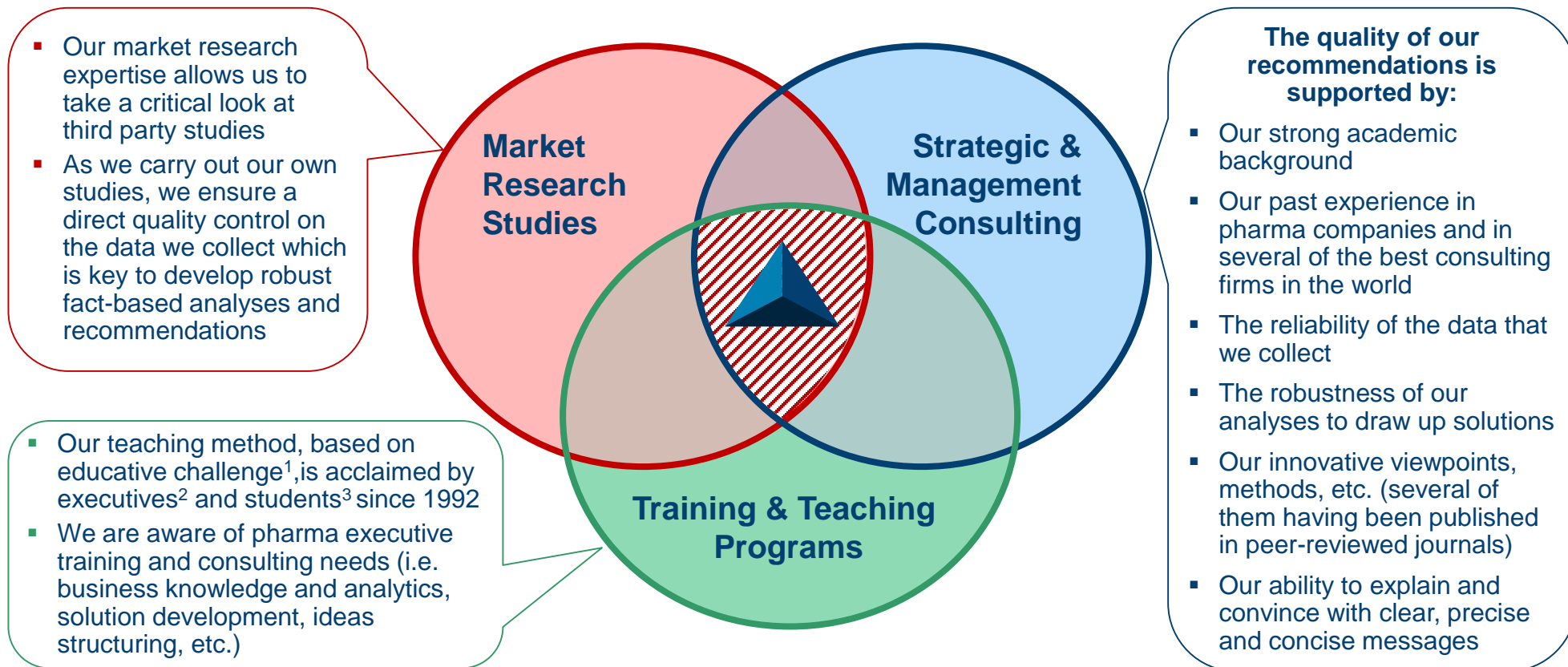
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**Key features**

- For the past 17 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**



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

The following selection of concepts / methods, tools and opinions, that are available on our website<sup>1</sup>, illustrates our “innovative power”

### Smart Pharma Consulting innovations

	Concepts / Methods	Tools	Opinions
 <b>Strategy &amp; Management</b>	<ul style="list-style-type: none"> <li>4Ws (What, Why, so What, What to do?)</li> <li>Preference-driven Strategy</li> <li>Pharma Corporate Reputation</li> <li>The Smart Manager</li> </ul>	<ul style="list-style-type: none"> <li>Development Strategy Matrix</li> <li>Corporate ID Card</li> <li>Advanced SWOT</li> <li>Customer Preference Card</li> <li>Pharma Reputation Index</li> </ul>	<ul style="list-style-type: none"> <li><i>The mirage of the BRICs<sup>2</sup></i></li> </ul>
 <b>Marketing &amp; Sales</b>	<ul style="list-style-type: none"> <li>4Ws</li> <li>Brand Booster Program</li> <li>Segmentation</li> <li>KAM Expert Wheel</li> <li>The ELITE Program</li> </ul>	<ul style="list-style-type: none"> <li>Brand Preference Mix Index</li> <li>Behavioral Prescriber Segmentation (BPS)</li> <li>KEIs<sup>3</sup> vs. KPIs<sup>4</sup></li> <li>Portfolio Strategic Matrix</li> <li>High Impact Interactions (H2I)</li> </ul>	<ul style="list-style-type: none"> <li><i>Brand preference supersedes brand satisfaction</i></li> <li><i>Med reps are key to drive physician preference</i></li> </ul>
 <b>Medical</b>	<ul style="list-style-type: none"> <li>4Ws</li> </ul>	<ul style="list-style-type: none"> <li>KOL ID Card</li> <li>KOL Partnership Plan (K2P)</li> <li>Integrated Regional Strategic Plan</li> </ul>	<ul style="list-style-type: none"> <li>NA</li> </ul>



## Introduction

- International healthcare expenditure
- Global pharma market (2016 – 2022)

## 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
- Community hospitable territory (GHT)
- Market access to new drugs – International comparisons
- National health insurance fund instances
- Complementary health cover organizations
- Regional health bodies
- Healthcare professionals and facilities
- Hospital financing 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
- New regulations towards generics and biosimilars
- Measures to limit the financial impact of expensive drugs
- 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
- LFSS 2018 main savings measures

### 1.3. Healthcare expenditure

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

## Section 2. The French pharmaceutical market

### 2.1. Evolution of drug sales

- Classification of pharmaceutical products in France
- Evolution of drug sales by segment (2012 – 2016)
- Hospital drug market dynamics (2012 – 2016)
- Evolution of drug sales by reimbursement rate (2011 – 2016)
- Top 10 therapeutic areas retail & hospital (2016)
- Top 10 products retail & hospital
- Sales of drugs on top “T2A” (2012 – 2016)
- The four status of “copies” in France
- Analysis of the regulation regarding the creation of generics group
- Molecules having lost their patent protection in 2016
- Evolution of reimbursable generics in the retail market
- Evolution of reimbursable generics market share in the retail market
- Evolution of reimbursable generics penetration in the retail market
- Public objectives of prescription within the generics Directory (2016)
- Savings generated by generics (2007 – 2016)
- Biosimilar drug market in France (2016)
- Evolution of the biosimilar market (2007 – 2016)
- OTC market size and structure (2016)
- Top 10 therapeutic areas in the OTC market (2016)
- Top 10 brands and umbrella brands in the OTC market (2016)
- Main barriers to the development of the OTC market in France

### 2.2. Evolution of pharma company sales

- Top 10 pharma companies retail and hospital market
- Top 10 pharma companies on the retail market
- Top 10 pharma companies on the hospital market
- Top 10 generics companies on the retail market
- Top 10 generics companies on the hospital market
- Top 10 generics companies on the OTC market

### 2.3. Future market trends

- Evolution of drug sales by segment (2012 – 2016 – 2022)
- Factors driving the evolution of drug sales by market segment (2016 – 2022)
- Drivers & limiters of biosimilars use by key stakeholders
- Determinants to biosimilar sales forecasts
- Evolution of the biosimilars market in France (2016)
- Market value of classes/INN impacted by biosimilars (2016 – 2022)
- Originators and biosimilars’ sales forecasts – Retail and hospital markets (2016 – 2022)



## Section 3. Strategic priorities for pharma companies

### 3.1. Introduction (7 Ps)

### 3.2. Policy makers & Payers

- 2016-2022 trends
- Driving factors
- Implications
- Strategic priorities

### 3.3. Physicians

- 2016-2022 trends
- Driving factors
- Implications
- Strategic priorities

### 3.4. Pharmacists

- Levers and solutions to improve the economy of pharmacies
- 2016-2022 trends
- Driving factors
- Implications
- Strategic priorities

### 3.5. Patients & PAGs

- 2016-2022 trends
- Driving factors
- Implications
- Strategic priorities

### 3.6. Pharma competitors

- 2016-2022 trends
- Driving factors
- Implications
- Strategic priorities

## Conclusion

## Glossary

**This report analyzes the current situation and the key trends of the French Pharma market by the end of 2022 to provide pharma companies with key strategic insights**

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**2016 – 2022 French pharma market prospects & strategic implications**

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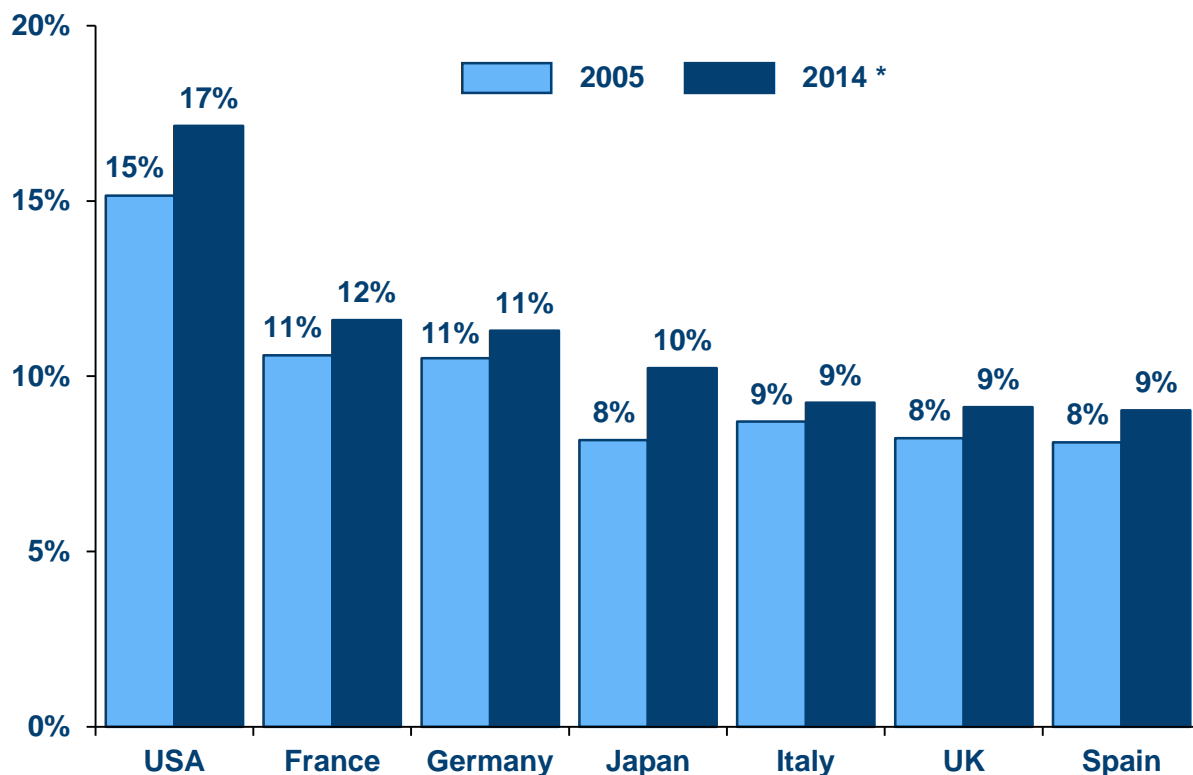
- Despite an ever tougher environment, the French pharma market will remain a key priority for pharma companies
- Smart Pharma Consulting proposes pharma companies to address the following key issues related to the French healthcare system and pharma market evolution by the end of 2022, to better grasp its strategic impacts



**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

Total healthcare expenditure as a % of GDP  
(Local currency)



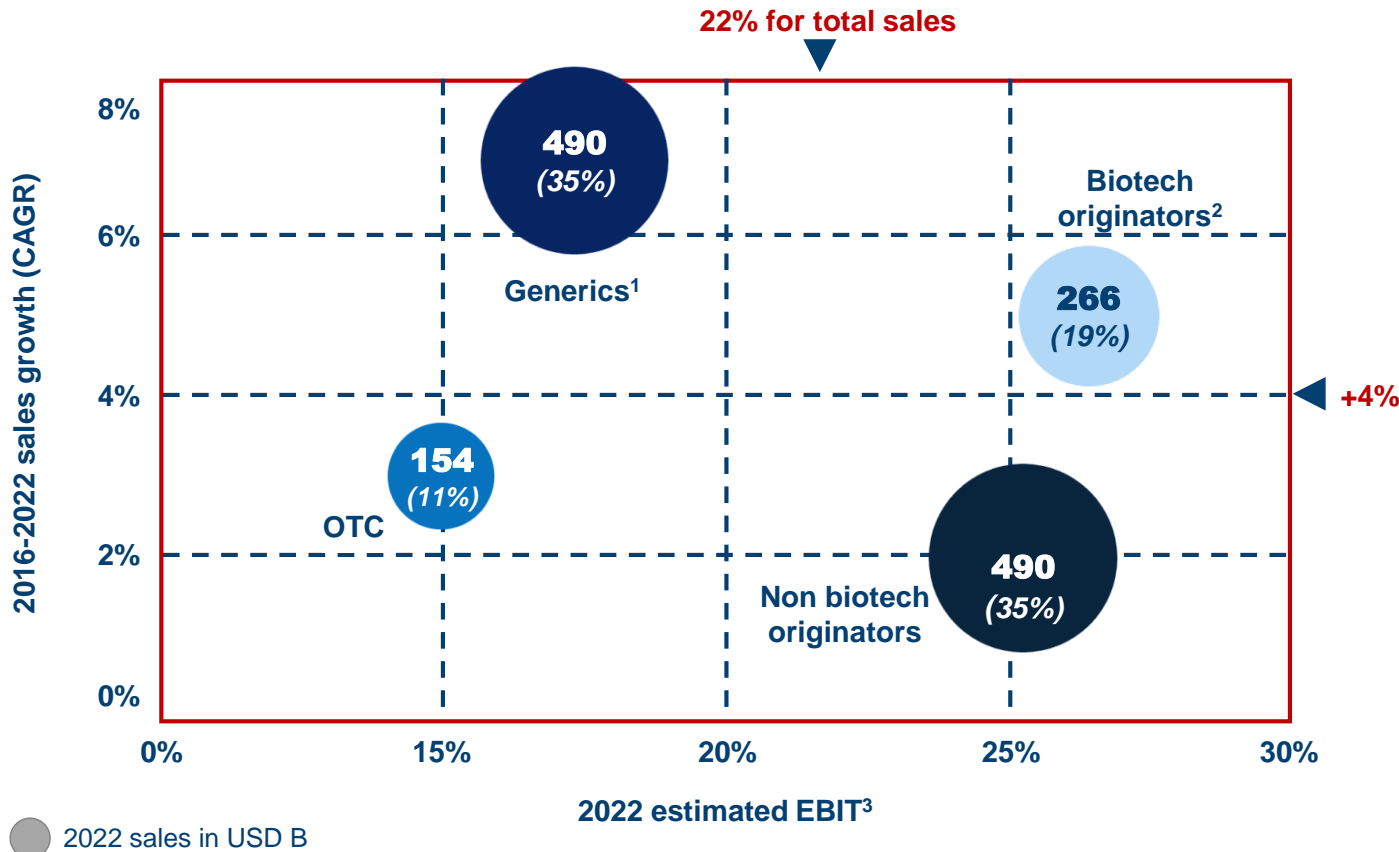
- Healthcare expenditure represented one of the largest public spending items in most developed economies: 1<sup>st</sup> (USA), 2<sup>nd</sup> (France, Germany, Japan, and UK)<sup>1</sup> and 3<sup>rd</sup> (Italy and Spain)<sup>2</sup>
- At best, governments and payers will manage to slow down the rise of healthcare expenditure as a percentage of GDP but would not be able to stop it
- 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

Sources: World Bank, as of September 2017 – OECD, as of September 2017 – Smart Pharma Consulting analyses

<sup>1</sup> After social protection – <sup>2</sup> After social protection and general public services  
\* Note: 2014 data excepted for France and the USA, 2015

**By 2022, the sales growth of pharma companies should be essentially driven by generic and innovative biologic drugs, but they should lose two points of profitability**

**Global pharmaceutical market attractiveness per strategic segment (2016 – 2022)**



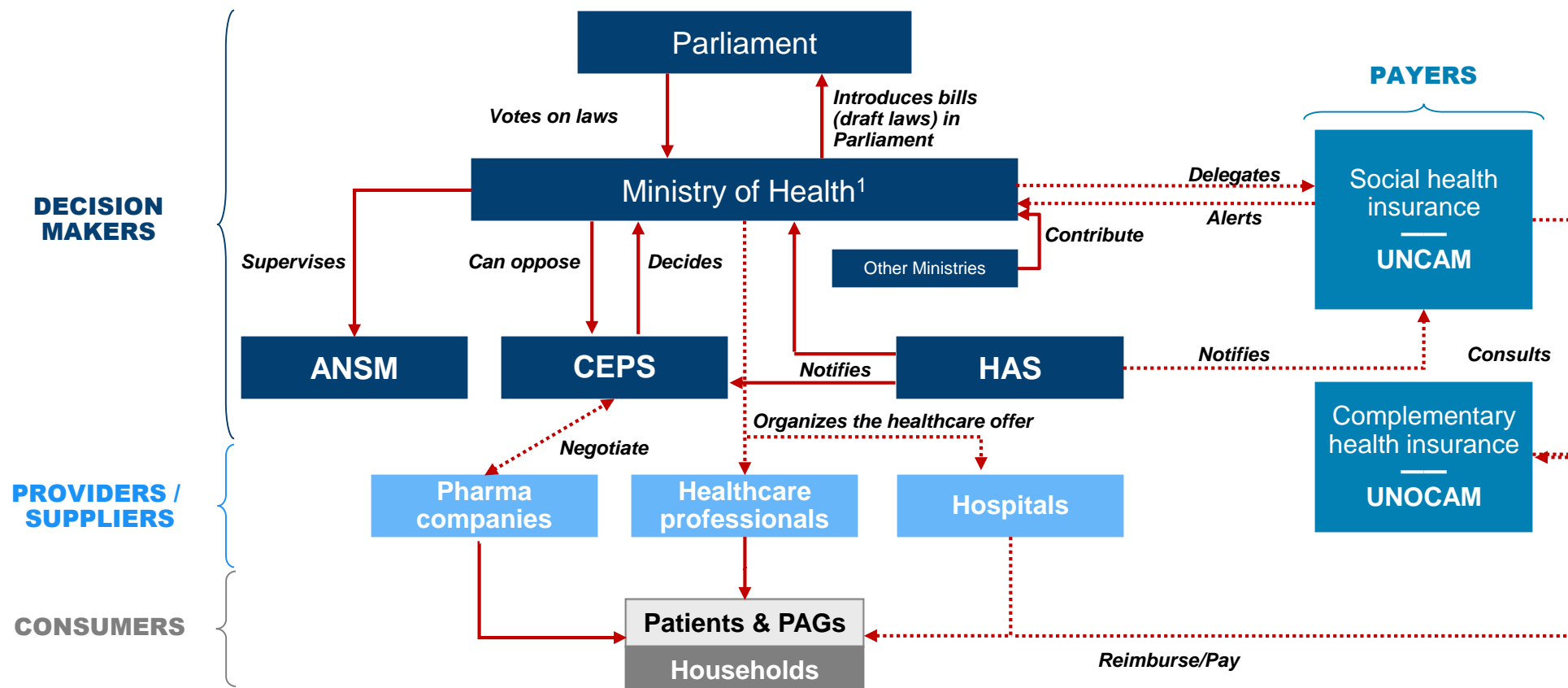
- By 2022, the sales (incl. human drugs only for the non-OTC segments and medical devices and food supplements for the OTC segment) should reach USD 1,400 B and grow at a pace of +4% p.a.
- Pharma companies EBIT should decrease from ~24% to ~22% over the period due to increased price pressure
- The OTC segment appears to be the least attractive
- The biotech segment will remain very attractive but biosimilar competition will ramp up

Sources: Outlook for Global Medicines through 2021, Quintiles IMS (December 2016) – Global OTC Drugs Market, Mordor Intelligence (August 2016) – Global economic prospects, World Bank (June 2017) – Smart Pharma Consulting estimates

<sup>1</sup> Including branded and unbranded generics and biosimilars, excluding OTC  
– <sup>2</sup> Excluding biosimilars, already included in the “Generics” segment –  
<sup>3</sup> Earnings before interests and taxes

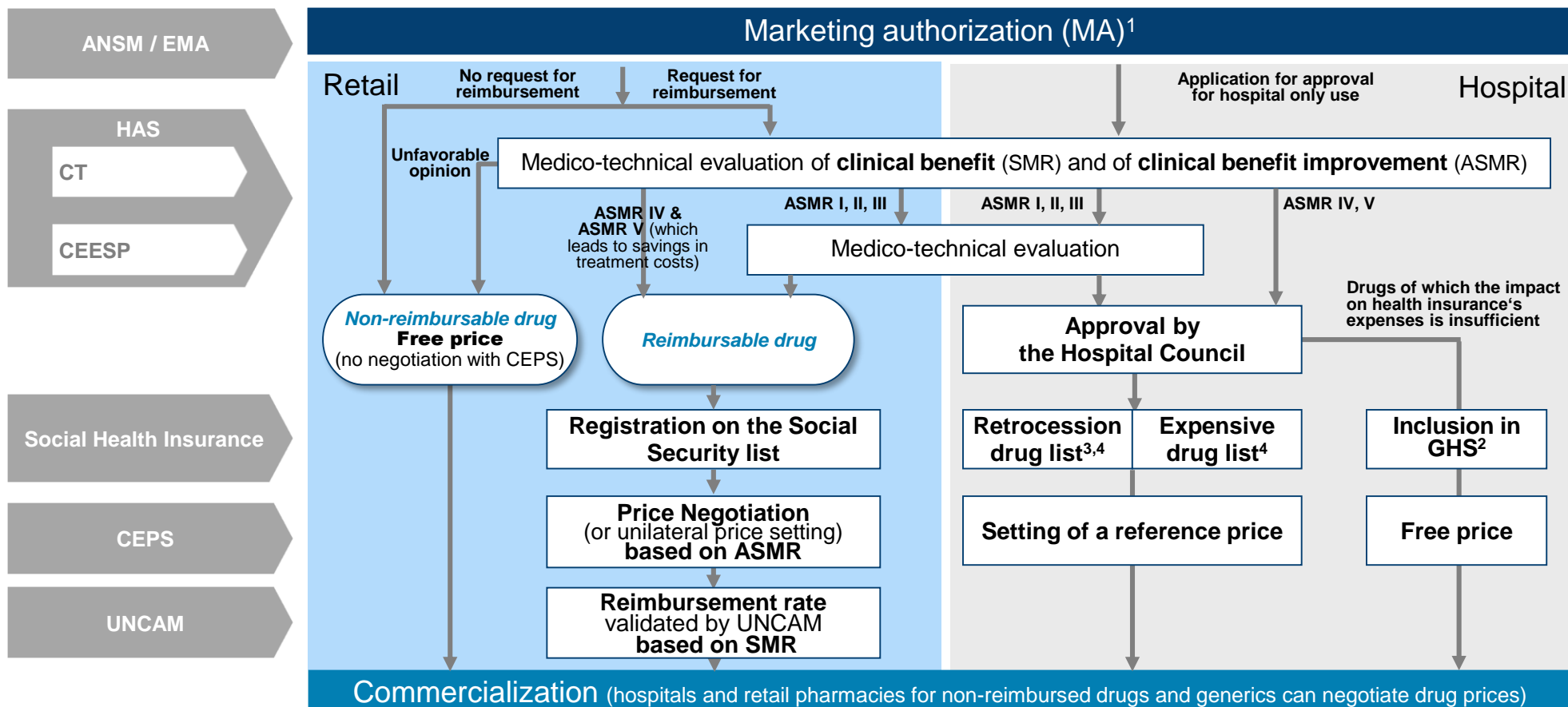
Stakeholders in the French healthcare system can be split according to their role as decision maker, payer, provider / supplier or consumer

### Mapping of key stakeholders



# Price and reimbursement settings depend on the status and on the clinical benefit of the drugs

## Overall reimbursement and pricing processes








Sources: Directive "Transparence" 89/105/CEE and updates – [www.anism.sante.fr](http://www.anism.sante.fr) – [www.leem.org](http://www.leem.org) – Smart Pharma Consulting analyses

<sup>1</sup> After a favorable opinion of the MA commission (national level) or the EMA (European level) – <sup>2</sup> Similar to Diagnosis-related groups (DRGs) – <sup>3</sup> These drugs can be dispensed to outpatients by hospital pharmacies – <sup>4</sup> The cost of these drugs is not covered by the hospital but by the Social Health Insurance

**When compared to the other EU5 countries, a wider array of indicators could be used by French health authorities to evaluate the economic value of drugs**

**CEESP – Health economic evaluations: Submission requirements in Europe**

	Therapeutic benefit	Cost-effectiveness modeling	Budget impact modeling	HRQoL <sup>1</sup> data	Data vs. SoC <sup>2</sup>	Innovation	Comments
	✓	✓	✓	✓	✓	✓	Cost-effectiveness taken into account since 2013 with the creation of the CEESP (Economic committee for healthcare products)
	✓		✓	✓	✓		Free pricing during the first six months on the market: i.e. before the assessment by IQWiG (Institute for Quality and Efficiency in Health Care)
	✓	✓	✓	✓	✓		One of the first countries to implement a form of value-based pricing including cost-effectiveness and QoL (Quality of Life) data
	✓	✓ (national or regional requirement)	✓ (national and regional requirement)		✓	✓	Requirements may vary from a region to another
	✓	✓ (national or regional requirement)	✓ (national and regional requirement)		✓		Requirements may vary from a region to another

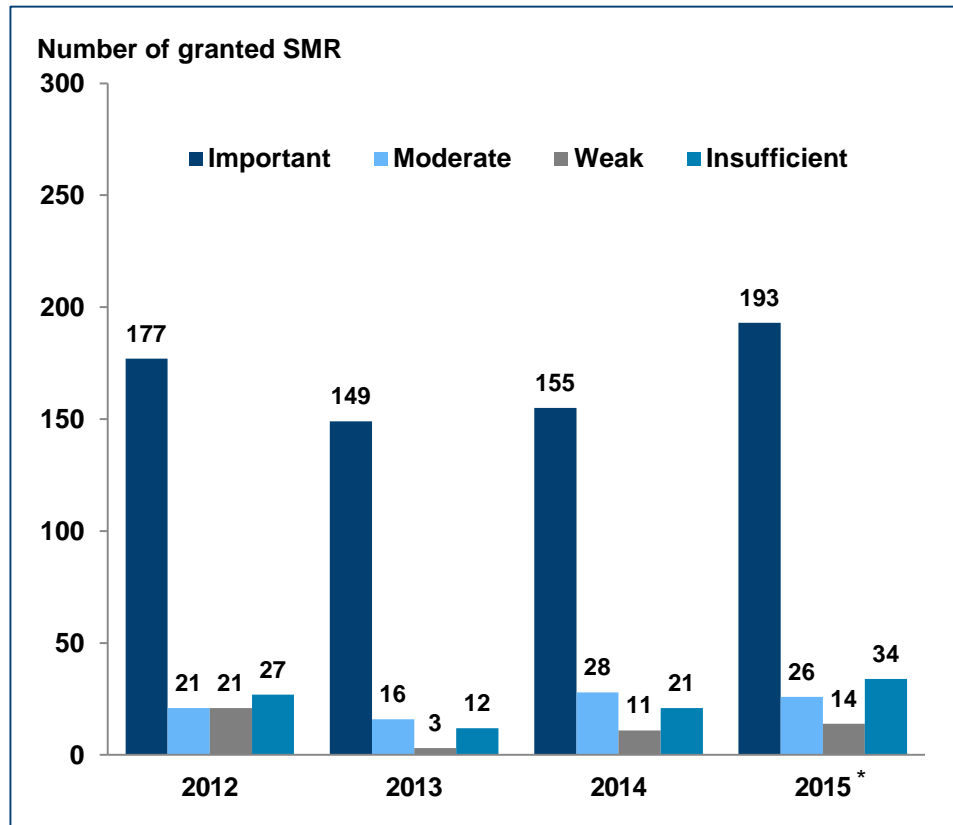
Sources: "An Introduction to European Market Access", PRMA Consulting – Smart Pharma Consulting updates

<sup>1</sup> Health-Related Quality of Life – <sup>2</sup> Standard of Care

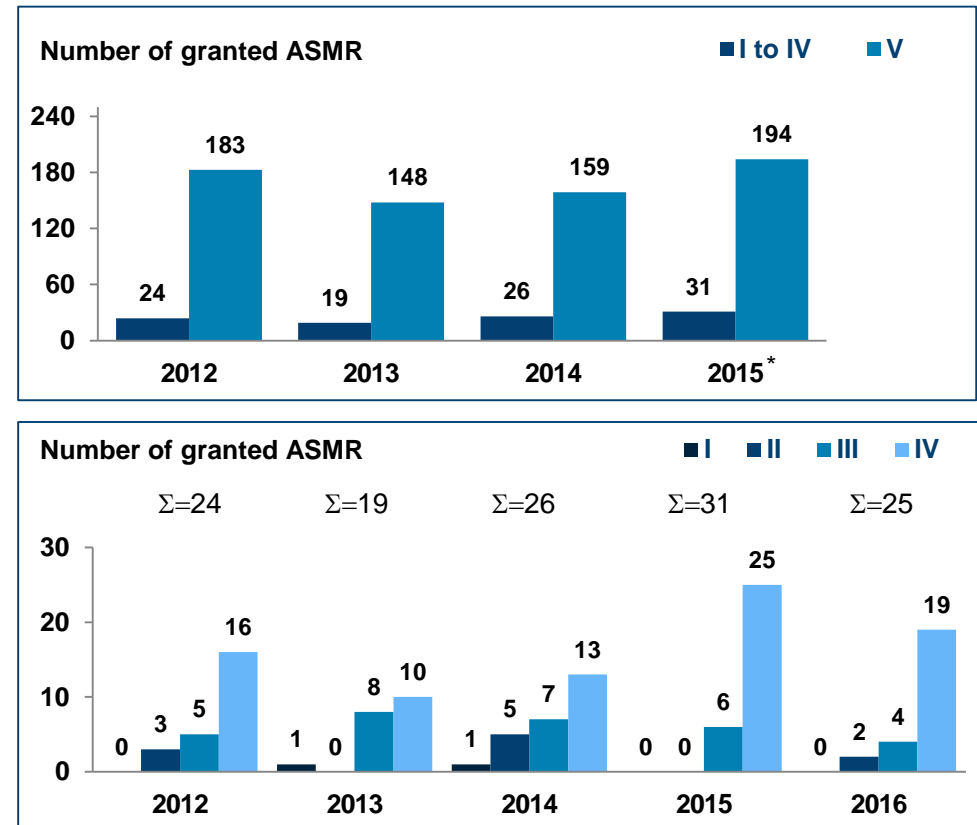
**French health authorities will keep on limiting the number of ASMR I, II & III to quantum leap innovations in order to contain the cost of reimbursed drugs**

**CT – SMR and ASMR granting over time (2012 – 2016)**

**Distribution of granted SMR levels<sup>1</sup>**



**Distribution of granted ASMR levels<sup>1</sup>**



\*2016 data not available in September 2017

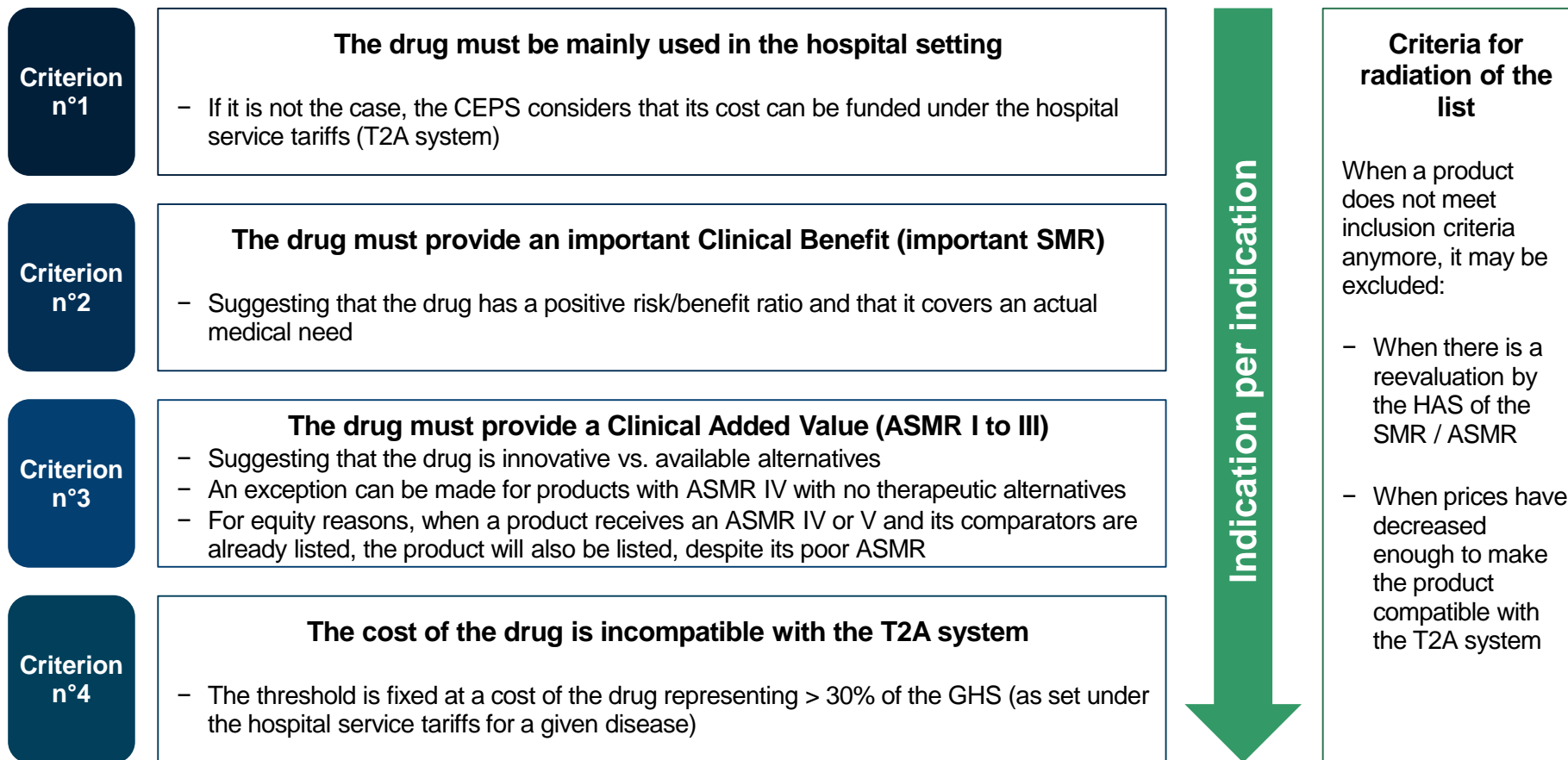
Sources: HAS Annual Activity Reports (2011-2016) – Smart Pharma Consulting analyses

<sup>1</sup> Applications for first registration only, all procedures combined. An application may result in several different SMR / ASMR, depending on the considered indications



## The criteria for the inclusion of a hospital drug on the list for invoicing on top of “T2A<sup>1</sup>” are well defined since March 2016

### — CEPS – Criteria for inscription on / radiation of the list of Off-T2A<sup>1</sup> expensive hospital drugs —

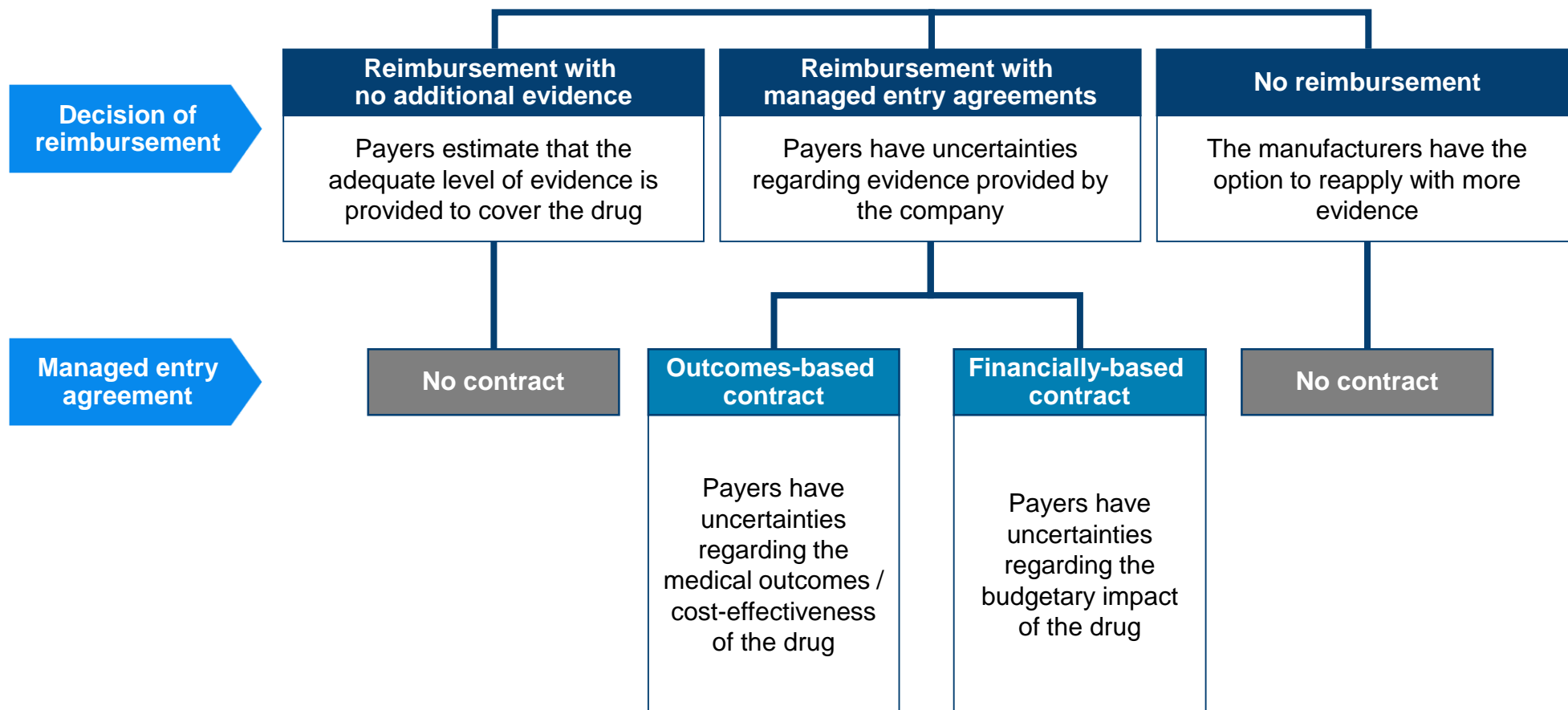


Sources: Decree of March 25<sup>th</sup>, 2016 regarding modalities of inscription to the “liste en sus” – Smart Pharma Consulting analyses

<sup>1</sup> Activity-based costing system similar to a Diagnosis related group-based funding

**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**



Sources: "Can't Get No Satisfaction? Will Pay for Performance Help? Toward an Economic Framework for Understanding Performance-Based Risk-Sharing Agreements for Innovative Medical Products", Adrian Towse and Louis P. Garrison Jr, 2010

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

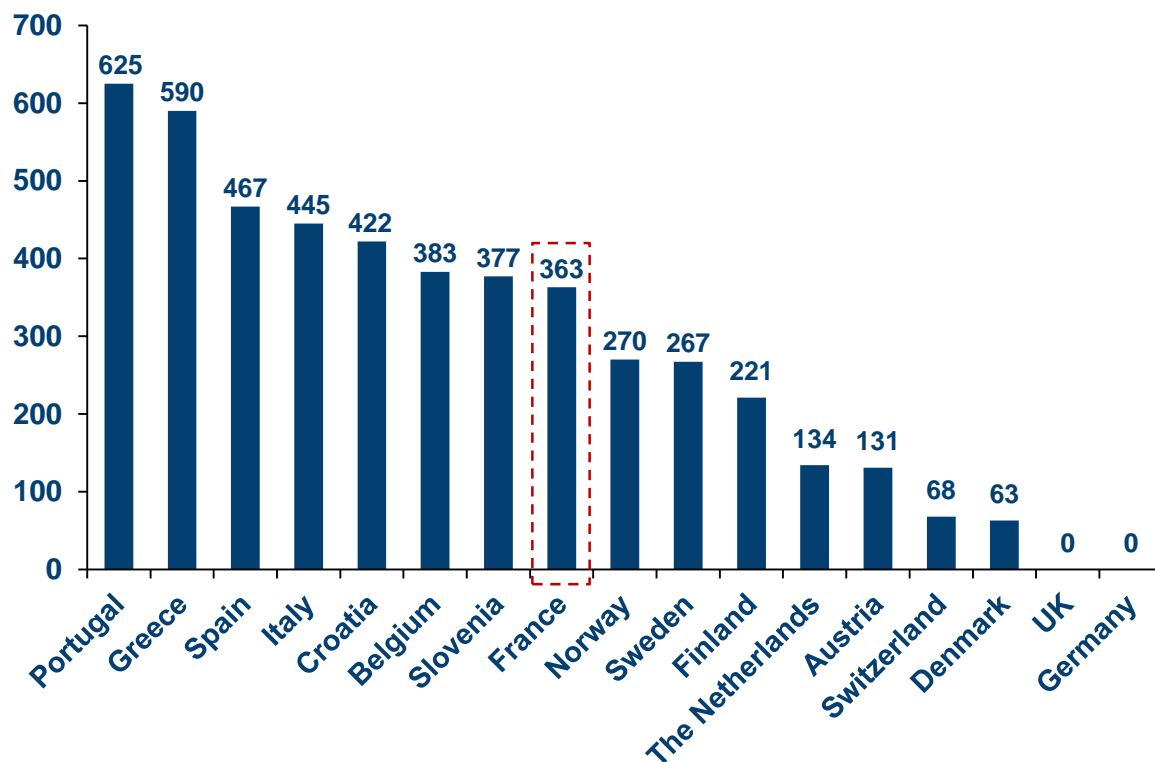
	Pros	Cons
CEPS	<ul style="list-style-type: none"> <li>Potential to <b>re-evaluate</b> the effectiveness of drugs at a later stage and <b>re-negotiate</b> the price based on <b>real-world evidence</b></li> <li>Help <b>address post-licensing uncertainty</b> by offering flexibility in dealing with new and often expensive treatments</li> <li>Improve the <b>cost-effectiveness</b> through a <b>discount</b> or a <b>payback</b> agreement for non-responders</li> <li>Enable <b>different types of schemes</b> addressing <b>different needs</b>, both <b>financial</b> and <b>non financial</b></li> </ul>	<ul style="list-style-type: none"> <li><b>Additional efforts</b> required to make a new drug available to patients, such as <b>negotiation time, monitoring of patient response, data gathering</b>, development of <b>registries</b>, etc.</li> <li>Threat that manufacturers could start proposing <b>higher entry prices</b> in the expectancy of having to engage managed entry agreements</li> <li><b>Limited capacity to implement</b> and <b>assess evidence</b>, notably if implementation takes place at regional/hospital level</li> </ul>
Pharma companies	<ul style="list-style-type: none"> <li>Speed up <b>pricing</b> negotiations and <b>reimbursement</b></li> <li>Potential to benefit from a better <b>corporate reputation</b> as a result of the willingness to take responsibility for the use of the drug in real-life</li> <li>Potential to <b>reinforce</b> the <b>long-term collaboration</b> between <b>payers</b>, <b>health authorities</b> and <b>pharmaceutical companies</b></li> <li>Enable <b>discounts</b> without impacting list prices</li> </ul>	<ul style="list-style-type: none"> <li><b>Costs</b> related to the implementation of the managed entry agreement can, in some cases, totally <b>outweigh benefits</b></li> <li><b>Concessions</b> required such as refunds for non-respondent patients, discounts, gathering of additional data</li> <li>Voluntary versus no voluntary nature of such contracts leading to a <b>variability in stakeholders' perception</b></li> </ul>

Sources: "Managed entry agreements for pharmaceuticals: the European experience", Alessandra Ferrario and Panos Kanavos, April 2013 – Smart Pharma Consulting analyses

**In eight European countries, including France, pharma companies and patients must wait, one year or more, after marketing authorization, to get a new drug reimbursed<sup>1</sup>**

**Average time to market vs. European countries**

Median time in days between marketing authorization and price and reimbursement<sup>1,2</sup>



- 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<sup>1</sup>
- The UK and Germany have no delay since the price and reimbursement negotiations occur once the product has reached the market

Sources: Patients W.A.I.T. Indicator – EFPIA (2015)

<sup>1</sup> Excluding early access programs for breakthrough innovations (e.g. ATU / post-ATU in France) – <sup>2</sup> For drugs receiving their first marketing authorization between 2011 and 2014

If mutual funds are in a greater number, they are often smaller than private insurance companies and provident funds in terms of activity

### Complementary health cover organizations

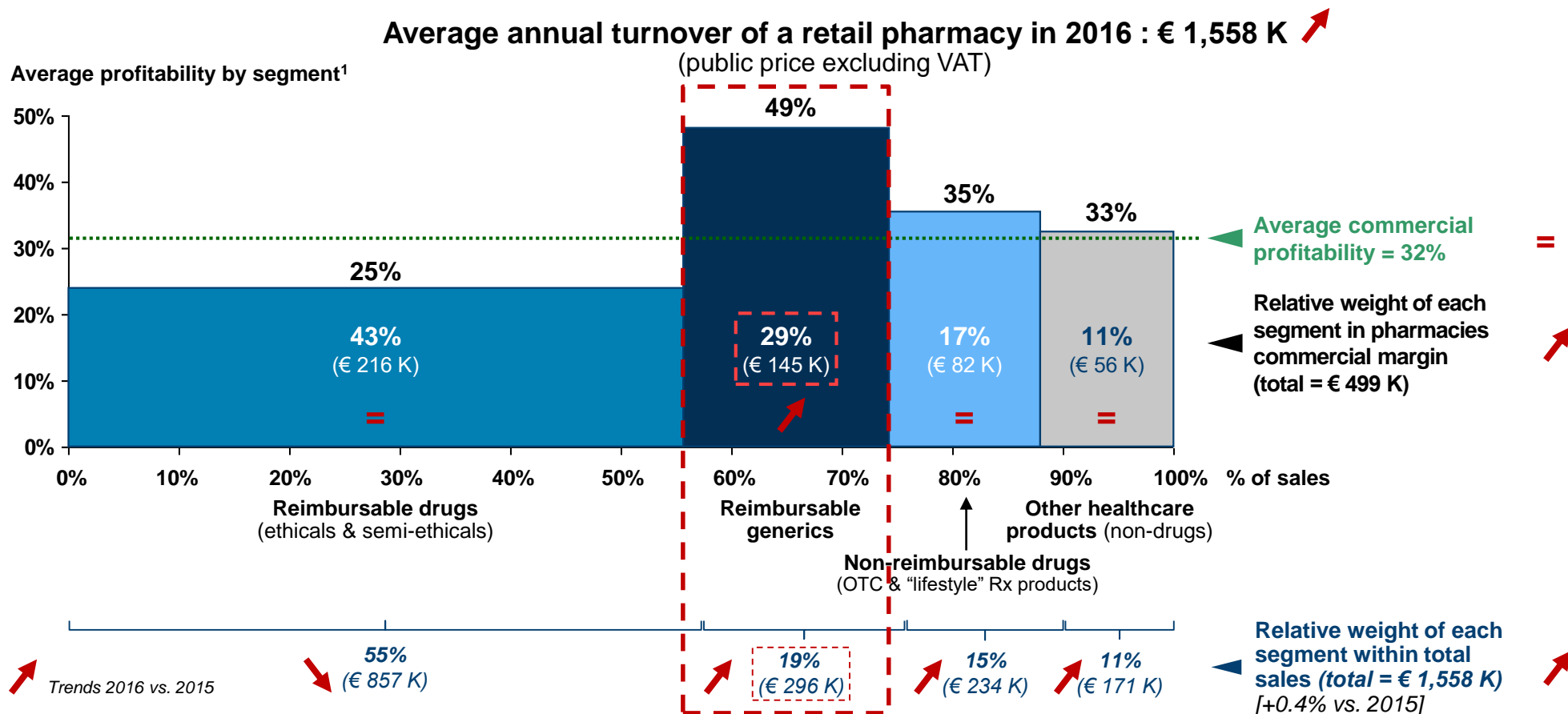
	Private organizations			Public schemes	
	Mutual fund	Provident funds	Private insurers	CMU Fund <sup>1</sup>	State medical assistance (AME)
Legal status	Private non-profit organization	Private non-profit organization	Private for-profit organization	Public institution of administrative nature	Private non-profit organizations (managed by the CPAM <sup>4</sup> )
Applicable law	Mutual societies code	Social Security code	Insurance code	Social Security code	Social Action and Families code
Description	<ul style="list-style-type: none"> <li>Self-management</li> <li>No discrimination based on health status of the person</li> <li>Level of contributions independent of the health status of the person</li> <li>The complementary health cover accounts for 2/3 of the activity of the mutual funds</li> </ul>	<ul style="list-style-type: none"> <li>Equal management (employee members and employer/company representatives)</li> <li>They are based on a collective company agreement</li> <li>Subscription of employees is not always mandatory</li> </ul>	<ul style="list-style-type: none"> <li>Non-participatory management</li> <li>No social mission</li> <li>Underwriting</li> <li>Amount of variable premiums based on the individual risk of the participant</li> <li>Optional membership on an individual or collective basis</li> </ul>	<ul style="list-style-type: none"> <li>Financing of the CMU-C<sup>2</sup> and ACS<sup>3</sup>: <ul style="list-style-type: none"> <li>Support the out of pocket of a basket of goods and health services for CMU beneficiaries with a lower level of resources ceiling</li> <li>CMU-C and ACS are agreed for one year</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Financing 100% of maternity care and disease (excluding treatments with low medical service)</li> <li>The AME is granted to foreigners in an irregular situation living in France for at least three months under the same conditions of resources than the CMU-C and after the payment of an annual fee of € 30</li> </ul>
% of organizations	74%	6%	20%		
% of insured people	58%	17%	25%		

Sources: "La protection sociale complémentaire en France", Irdes (July 2017) – Fonds CMU (www.cmu.fr) – Smart Pharma Consulting

<sup>1</sup> Universal Medical Coverage (for people regularly and stably living in France and not entitled to Health Insurance) – <sup>2</sup> Complementary universal health cover – <sup>3</sup> Help for a complementary fund, for people exceeding the ceiling of CMU-C within the limit of 26% – <sup>4</sup> Local Healthcare Insurance Body

**In 2016, generics accounted for 19% of the retail pharmacies' sales on average and for 29% of their margin, due to the high rebates offered by generics companies**

**Economic structure of retail pharmacies in France (2016)**



Sources: KPMG (2016) – Smart Pharma Consulting analyses

<sup>1</sup> Inclusive of legal margin, rebates, commercial agreements and remuneration for pharmaceutical services, notably those corresponding to the public health objectives (e.g. generics substitution objectives, pharmaceutical interviews with patients, etc.)

## Former Health Minister, Marisol Touraine, made the Health System Modernization Act be enacted from January 26<sup>th</sup>, 2016

### Health System Modernization Act

*“One objective: **equality**. Only one method: **innovation**”, Marisol Touraine*

<b>Priority 1: “Innovate to better prevent”</b> Prevention should be at the heart of the healthcare system	<b>Priority 2: “Innovate to better care in close proximity”</b> Redirecting the health system on community-based care	<b>Priority 3: “Innovate to strengthen patients rights and safety”</b> New concrete rights to patients, progression of health democracy and reinforced patients' safety
<ul style="list-style-type: none"> <li>▪ <b>Measure 1:</b> Deploy a health education pathway from kindergarten to high school</li> <li>▪ <b>Measure 2:</b> Refer to GPs for children (up to 16 years)</li> <li>▪ <b>Measure 3:</b> Strengthen nutrition information on food packaging</li> <li>▪ <b>Measure 4:</b> Reduce the phenomenon of massive alcoholism among young people</li> <li>▪ <b>Measure 5:</b> Actively fight against smoking</li> <li>▪ <b>Measure 6:</b> Improve screening for sexually transmitted infections</li> <li>▪ <b>Measure 7:</b> Encourage risk reduction among drug users</li> <li>▪ <b>7 other secondary measures</b>, including the access to emergency contraception for secondary level schools</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Measure 8:</b> Develop a community-based care around GPs</li> <li>▪ <b>Measure 9:</b> Set up a third-party payment system for physicians</li> <li>▪ <b>Measure 10:</b> Create a national helpline to call on-call physicians</li> <li>▪ <b>Measure 11:</b> Expand the competencies of selected health professions</li> <li>▪ <b>Measure 12:</b> Relaunch the “shared medical record”</li> <li>▪ <b>Measure 13:</b> Strengthen the “public hospital service”</li> <li>▪ <b>4 other secondary measures</b>, including the creation of GHT<sup>1</sup></li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Measure 14:</b> Creating a right to oblivion for former patients with serious diseases</li> <li>▪ <b>Measure 15:</b> Allowing “class action” in healthcare</li> <li>▪ <b>Measure 16:</b> Improve access to abortion throughout the country</li> <li>▪ <b>Measure 17:</b> Open access to health data</li> <li>▪ <b>Measure 18:</b> Ensuring more transparency on links of interest in health</li> <li>▪ <b>Measure 19:</b> Increasing the safety of medicines and medical devices</li> <li>▪ <b>6 other secondary measures</b></li> </ul>

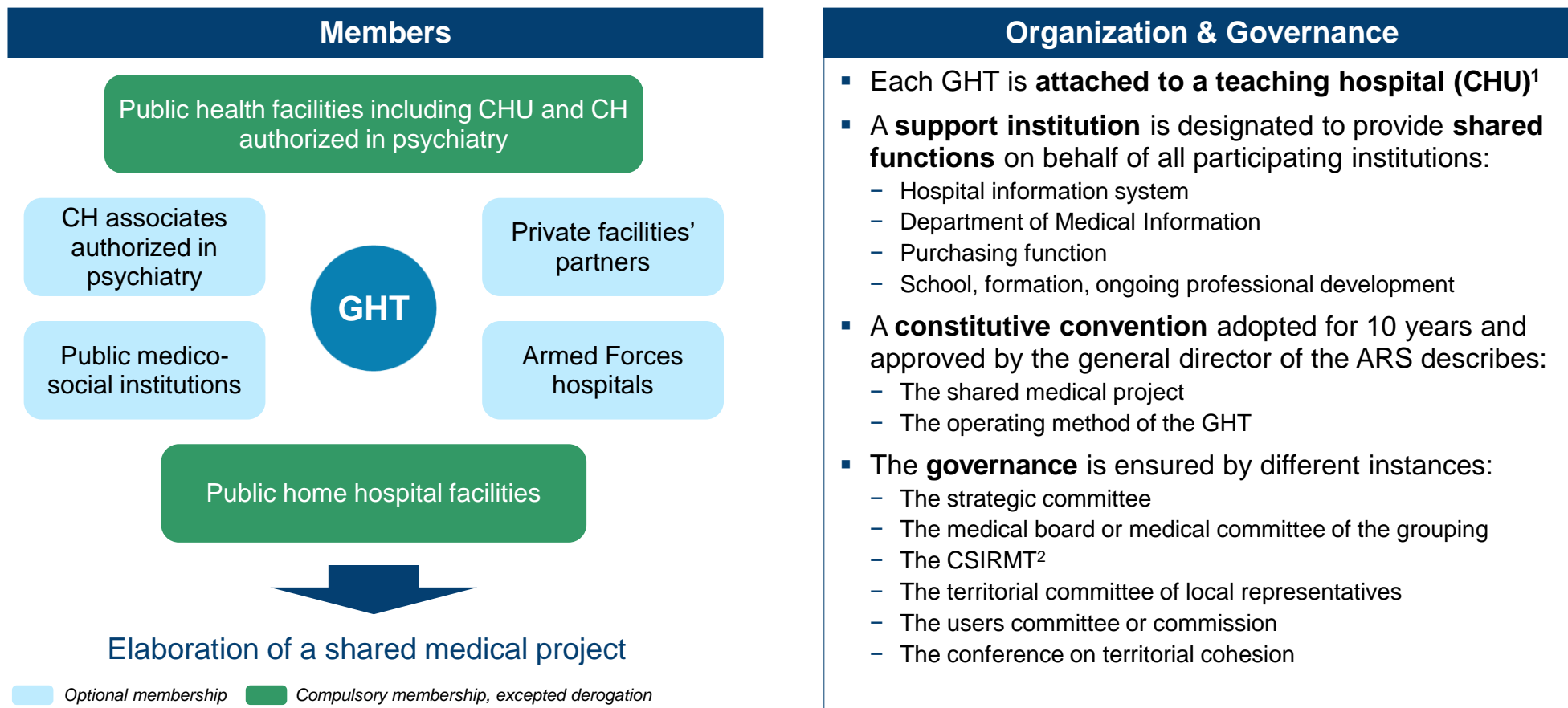
Sources: Press kit “Loi de Modernisation de notre système de Santé”, French Health ministry January 28<sup>th</sup>, 2016 – Smartt Pharma Consulting Analyses

<sup>1</sup> GHT: “Groupement Hospitalier de Territoire”: grouping which governs cooperation between several public health establishments in the same territory. 135 GHTs were created on July 5<sup>th</sup>, 2017



The shared medical project is the heart of the GHT because it guarantees a proximity and a reference offer

## GHT – Community hospitable territory



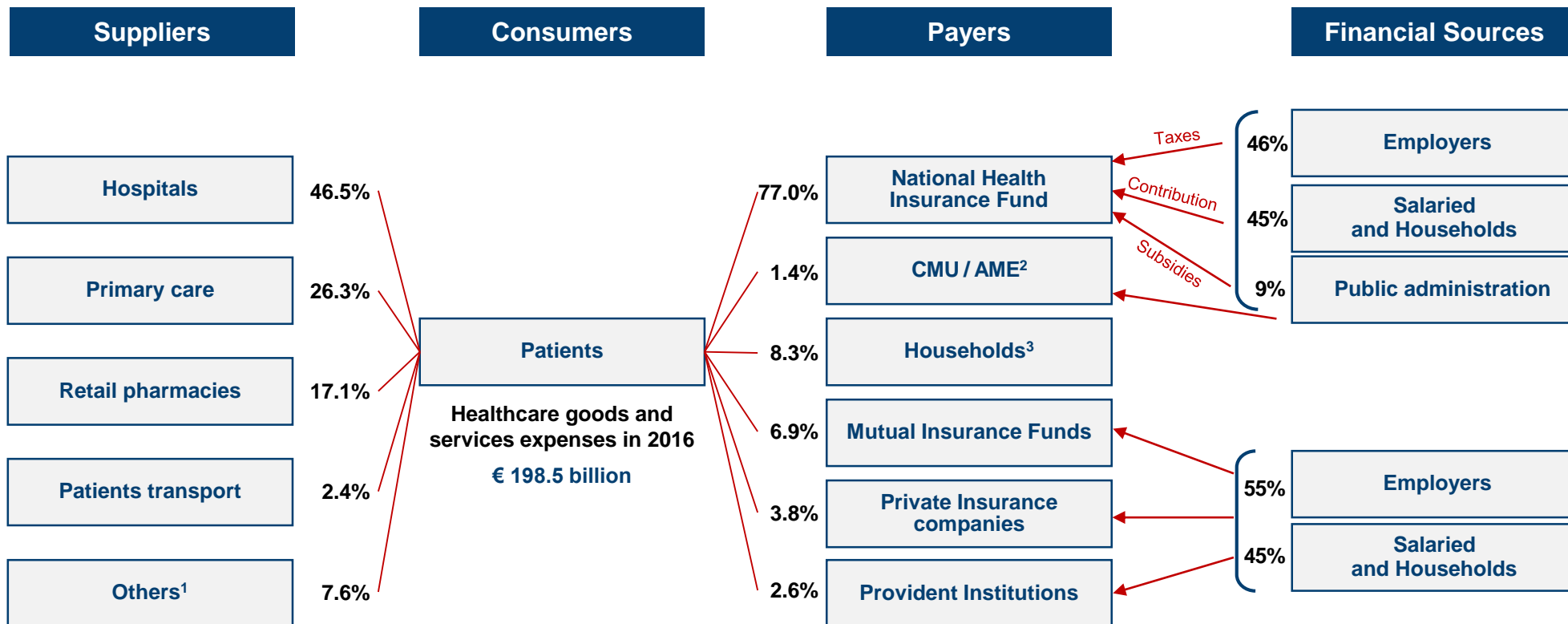
Sources: "Rapport intermédiaire de Jacqueline Hubert et de Frédéric Martineau sur les GHT", May 2015 – Smart Pharma Consulting Analyses

<sup>1</sup> A CHU may be part of a GHT and be associated with several other GHTs – <sup>2</sup> CSIRMT: "Commission des Soins Infirmiers, de Rééducation et Médico-Techniques": Commission on nursing, rehabilitation and medico-technical care



**In 2016, total expenditure for healthcare goods and services amounted to € 199 billion (of which ~47% from hospitals) and was mostly funded by the Social Security**

**Supply, consumption and funding of healthcare and medical goods in 2016**

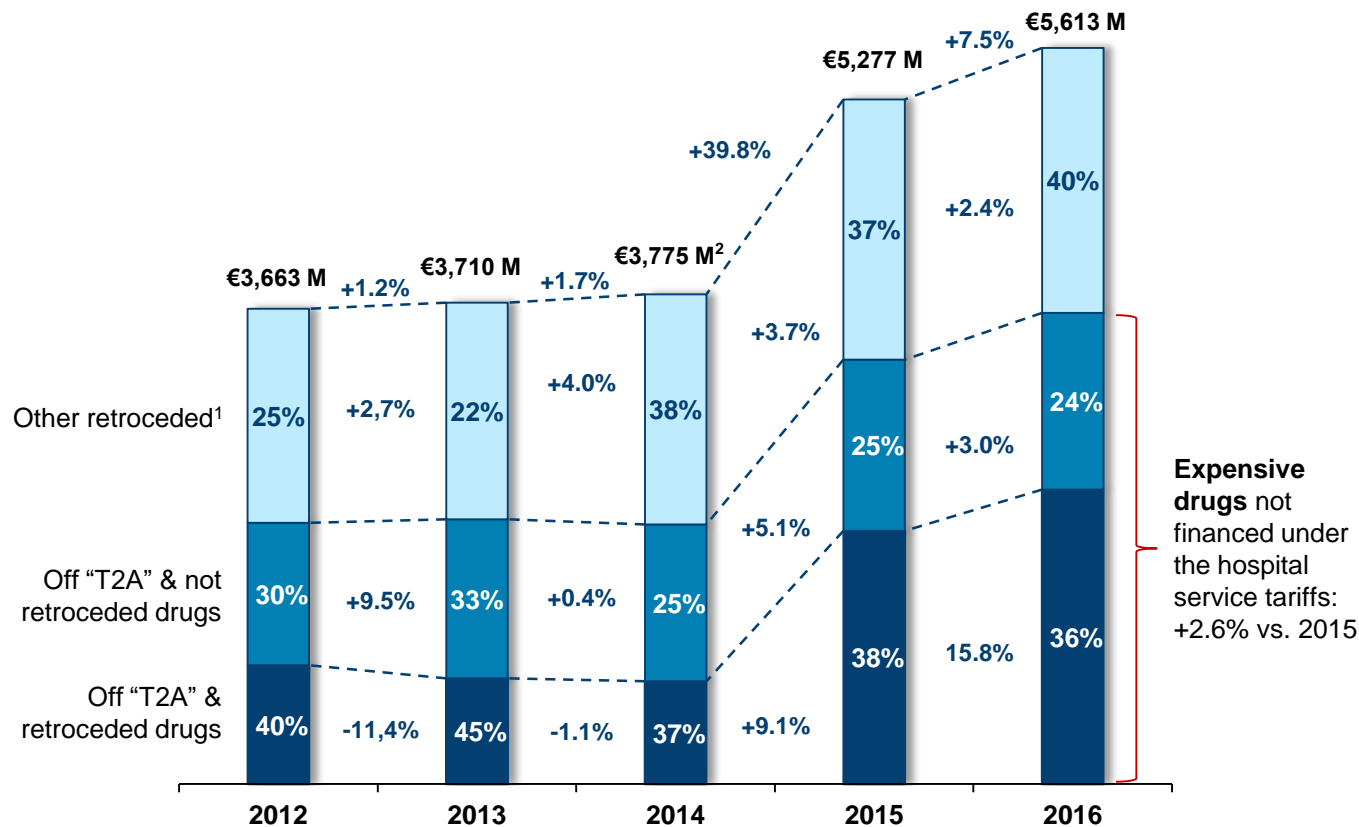


Sources: "Comptes nationaux de la santé 2016", DRESS – "Programme de qualité et d'efficience : Financement", Sécurité sociale 2017 – Smart Pharma Consulting analyses

<sup>1</sup> Optics, prostheses, small devices, hygiene and first aid, etc. – <sup>2</sup> CMU / AME: "Couverture Médicale Universelle Complémentaire / Aide Médicale d'Etat": Complementary universal medical coverage / State medical assistance – <sup>3</sup> Non reimbursed, deductible, etc.

The increase of on top of “T2A” drug sales was mainly driven by the growth of Imnovid, Imbruvica, Viekirax, Keytruda and Entyvio

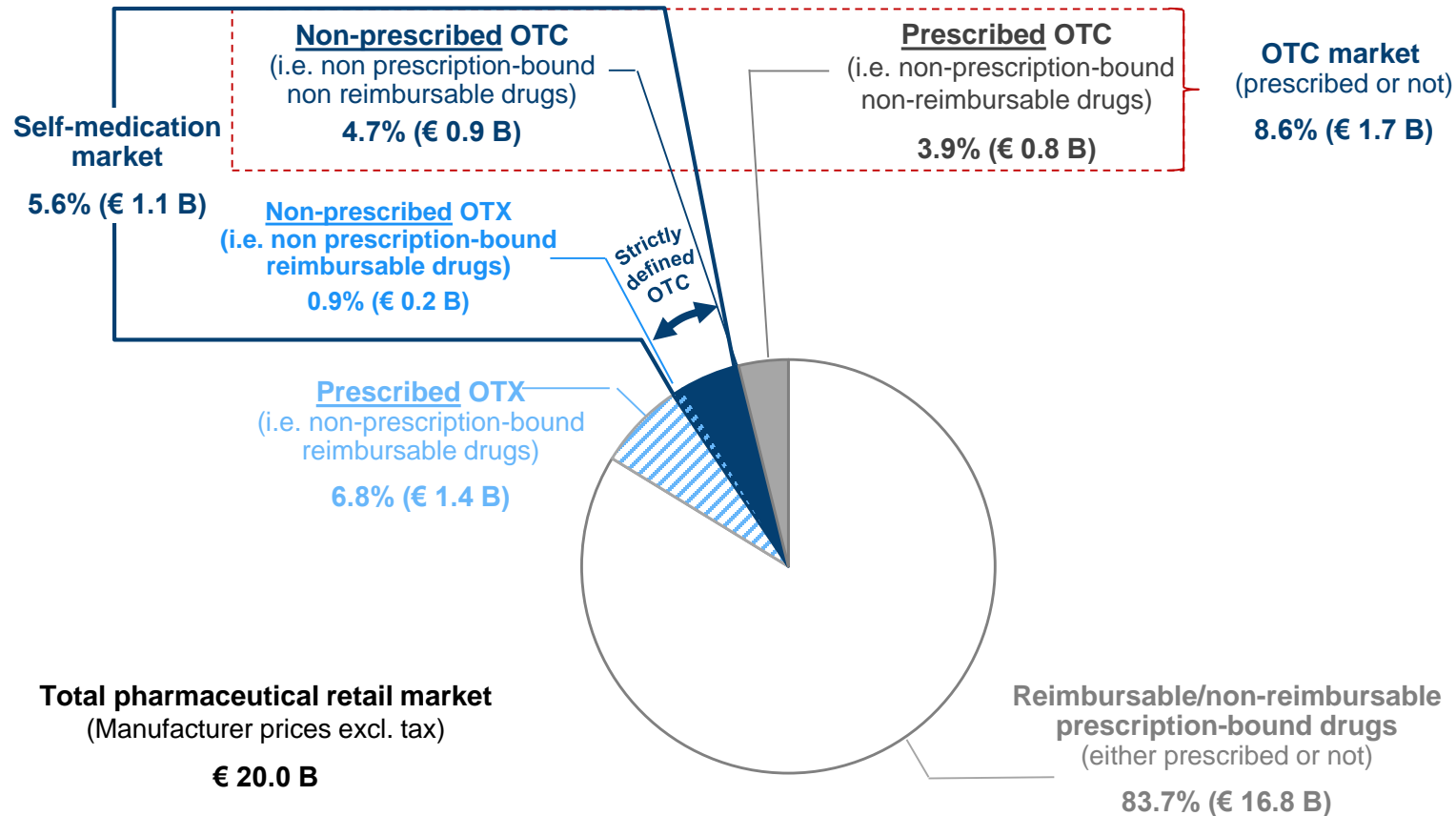
**Sales of drugs on top of “T2A” (2012 – 2016)**



- **Innovid** (Pomalidomid), monoclonal antibody used for multiple myeloma in relapse and refractory in adult patients, marketed by Celgene
- **Imbruvica** (Ibrutinib), monoclonal antibody for adults with leukemia marketed by Janssen
- **Viekirax** (Ombitasvir + Paritaprevir + Ritonavir), antiviral complex indicated for chronic hepatitis in adults, marketed by AbbVie
- **Keytruda** (Pembrolizumab), humanized monoclonal antibody for adult patients suffering from advanced melanoma and non-small-cell lung cancer, marketed by MSD
- **Entyvio** (Vedolizumab), humanized monoclonal antibody indicated for the treatment ulcerative colitis and Crohn’s disease, marketed by Takeda

In 2016, the self-medication market accounted for 5.6% of the retail pharmaceutical market and included both reimbursable and non-reimbursable non prescribed drugs

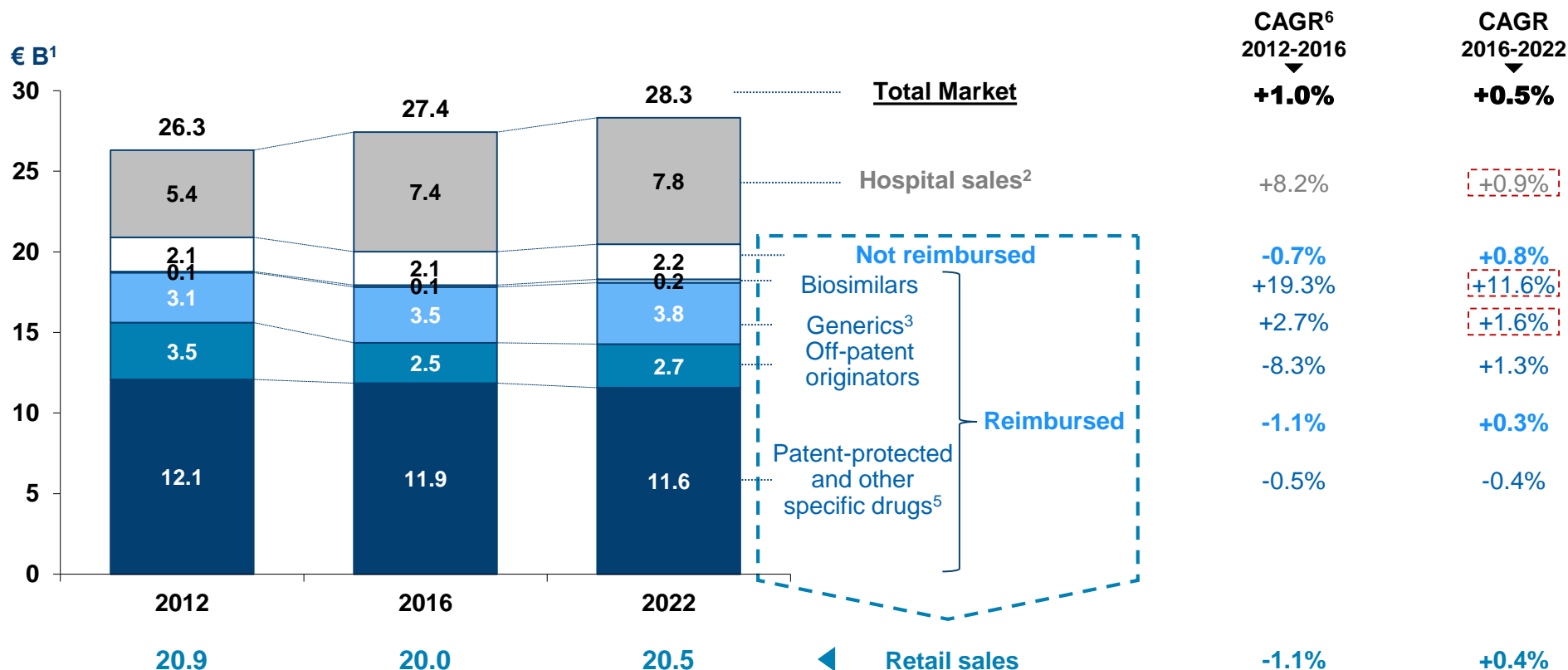
### OTC market size and structure (2016)



- 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

By 2022, the pharmaceutical market should be mainly driven by innovative hospital products, biosimilars and generics

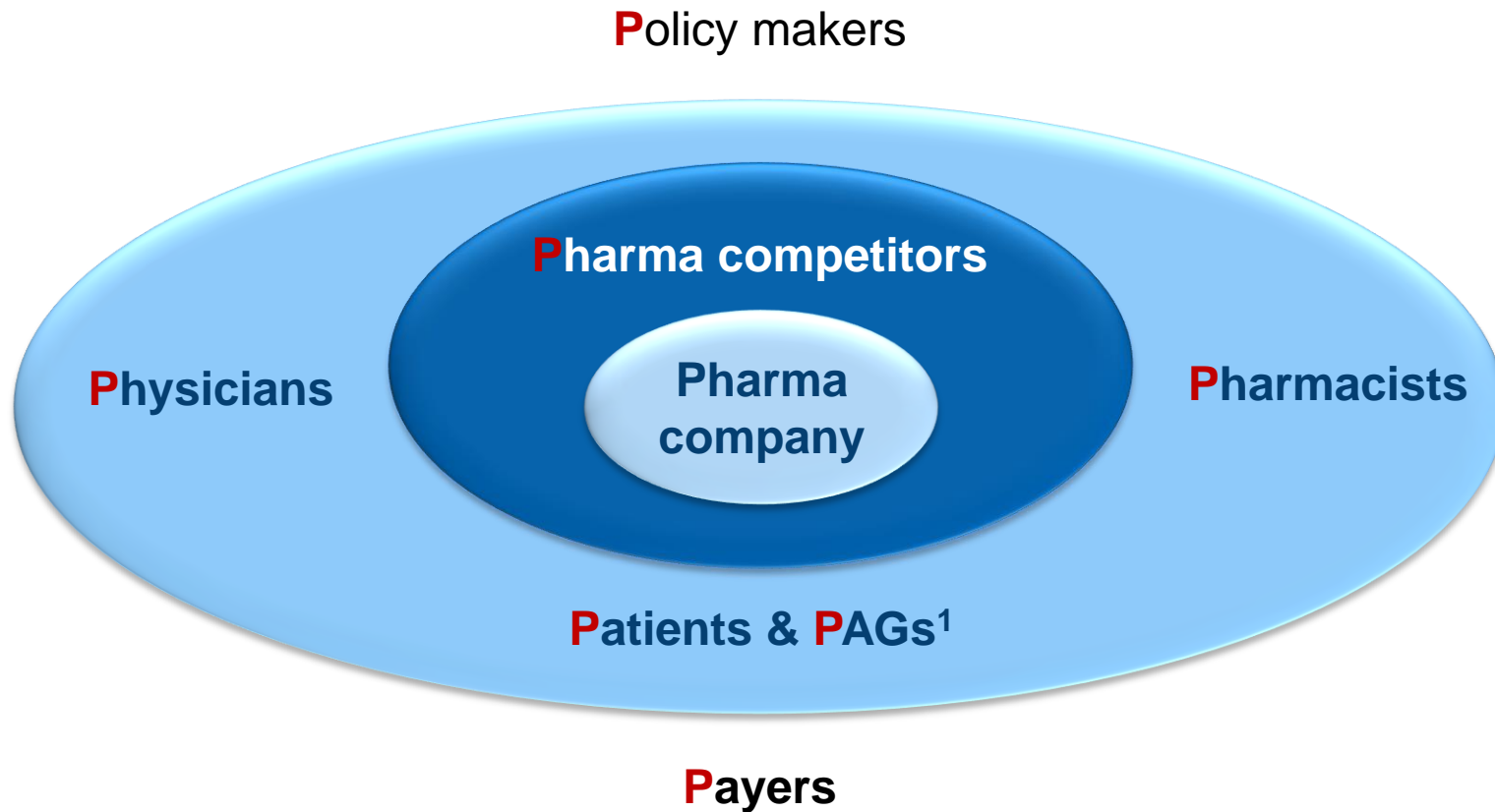
### Evolution of drug sales by segment (2012 – 2016 – 2022)



\* Hospital rebates are estimated to -30% of total hospital sales

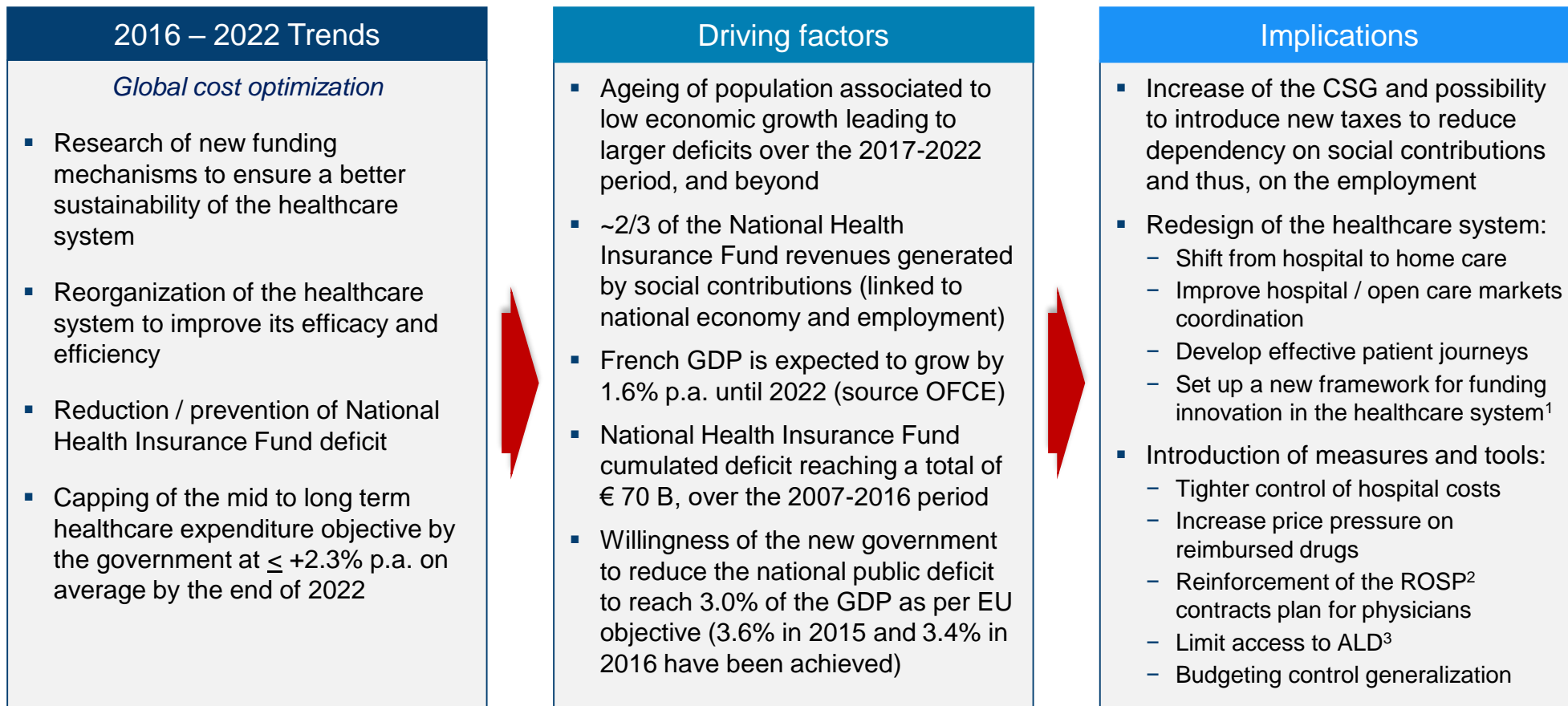
Pharmaceutical companies' strategic priorities by 2022 will be linked with the behavior of the “7 Ps” stakeholders

**The 7 Ps**



## 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)



Sources: LFSS 2018 – Smart Pharma Consulting analyses

<sup>1</sup> As addressed in the Article 51 of the LFSS 2018 – <sup>2</sup> Bonus program to encourage physicians to comply with “best prescribing practices” for a better efficacy/cost ratio – <sup>3</sup> 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**

**Behavioral trends**

- 1** **Stricter control of reimbursed drug expenditure**
- 2** **Measures to boost generics & biosimilars**
- 3** **Shift from hospital to ambulatory care**
- 4** **Promotion of R&D investments in France**

**Strategic priorities for pharma companies**

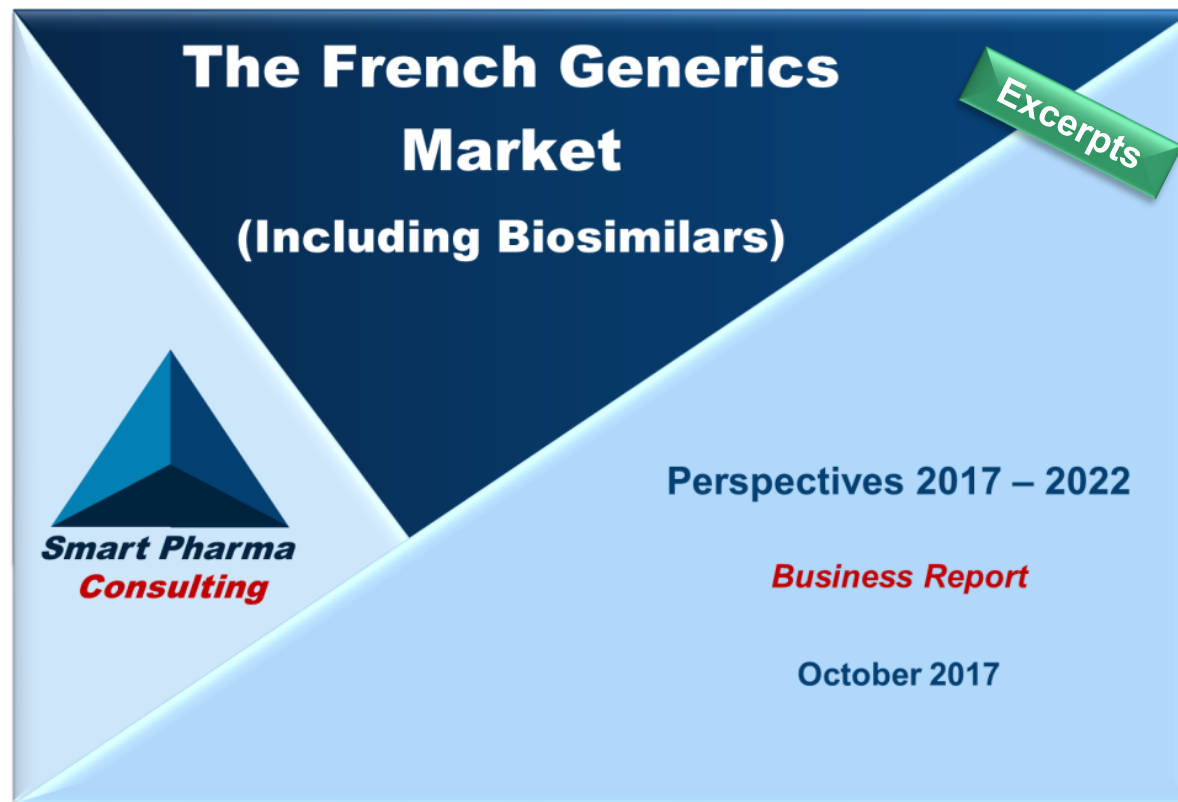
Enhance their global value proposition (incl. corporate identity, product and service offering) through:

- Dedicated corporate reputation programs targeted at policy makers and government
- Generation of RWD (Real Word Data) and ...
- ... high quality medico-economic studies (if relevant)
- Initiation / support of specific projects to improve patient care

Participate to working groups with health authorities and other stakeholders to:

- Facilitate the change management
- Ensure this change will have a positive, or at least a neutral effect, on pharma company performance

Increase or maintain R&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





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**This report describes and explains the dynamics of the French generics and biosimilars markets and evaluates their attractiveness by 2022**

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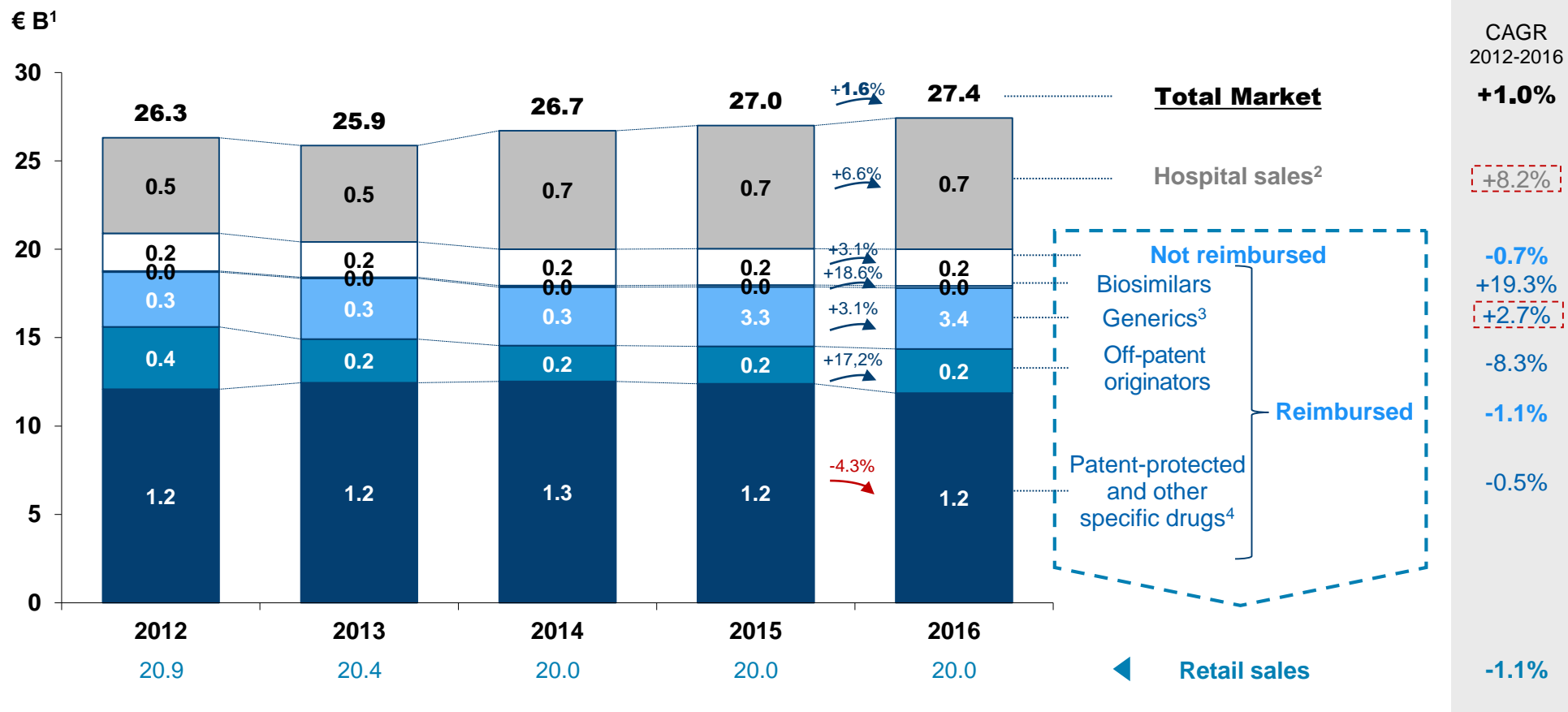
**Context & objectives**

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- **In this report, Smart Pharma Consulting proposes to cover the following questions:**
  - What is the definition and status of generics and biosimilars in France?
  - What are the recent dynamics, changes and trends on the retail and hospital markets?
  - What are the behaviors of the different stakeholders towards generics and biosimilars?
  - How should these behaviors evolve by 2022?
  - What are essentially similar drugs and what is their performance?
  - What is the performance of generics and biosimilars?
  - Who are the major generics and biosimilars manufacturers and their competitive position?
  - What are the main opportunities and threats on generics and biosimilars markets?
  - What would the French generics and biosimilars markets look like in 2022?

Spending on drugs is mainly driven by hospital sales and by generics sold in retail pharmacies

**Evolution of drug sales by segment (2012 – 2016)**



Sources: GERS and Top Pharma data – Smart Pharma Consulting analyses

<sup>1</sup> Constant ex-factory prices – <sup>2</sup> Estimated rebated sales including hospital sales of biosimilars and products invoiced on top of “T2A” and reassigned medicine sales – <sup>3</sup> Reimbursable generics and quasi-generics – <sup>4</sup> Sales of drugs whose patents have not expired and of other specific products (calcium, sodium, potassium, paracetamol, etc.)

**Substitution of biosimilars by retail pharmacists, at treatment initiation, is legal since 2014, but the absence of the corresponding decree does not allow its implementation**

### Characteristics of the four status of “copies” in France

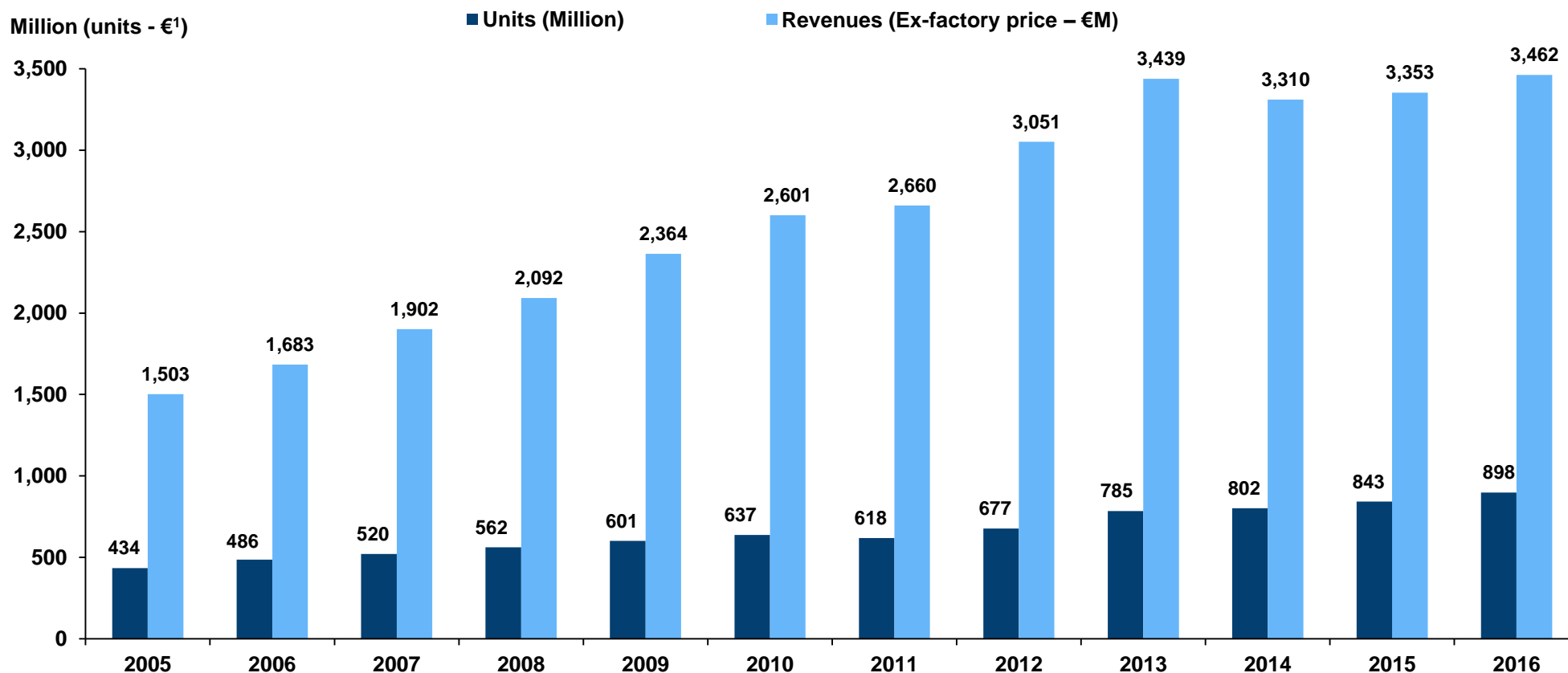
	Generics	Quasi-generics / Generic FOLM <sup>1</sup>	Essentially similar drugs	Biosimilar drugs
Description	<ul style="list-style-type: none"> <li>Copies of synthetic drugs</li> <li>Bioequivalence has been proven</li> </ul>	<ul style="list-style-type: none"> <li>Copies of oral modified release form drugs</li> <li>Bioequivalence (has not or) cannot be proven</li> </ul>	<ul style="list-style-type: none"> <li>Copies of synthetic drugs</li> <li>Bioequivalence (has not or) cannot be proven</li> </ul>	<ul style="list-style-type: none"> <li>Copies of biotech products</li> <li>Bioequivalence cannot be proven</li> </ul>
Market approval requirements	<ul style="list-style-type: none"> <li>Abridged procedure with simplified dossier reproducing original brand's clinical outcome</li> </ul>	<ul style="list-style-type: none"> <li>Same as for generics</li> <li>Necessity to respect the modified form of the originator (i.e. prolonged, delayed or sequential)</li> </ul>	<ul style="list-style-type: none"> <li>Minimal clinical development to document safety/ efficacy profile (e.g. with specific device used)</li> </ul>	<ul style="list-style-type: none"> <li>Complete clinical development (excluding phase 2 studies)</li> </ul>
Substitution <sup>2</sup>	Allowed	Allowed	To be allowed only at treatment initiation, pending application decree <sup>3</sup>	To be allowed only at treatment initiation, pending application decree
Examples	OMEPRazole MYLAN (generic of MOPRAL)	ESOMEPRazole BIOGARAN (Quasi-generic of INEXIUM)	VITALOGINK (Essentially similar of TANAKAN)	BINOCRIT (Biosimilar of EPREX)

Sources: Legifrance , Article L.5125-23 CSP – Senate, November 2016 – LFSS 2017 – Smart Pharma Consulting analyses

<sup>1</sup> “Formes orales à libération modifiée” = Modified-release oral forms – <sup>2</sup> Substitution of original brands by their generic / essentially similar / biosimilar drug, in retail pharmacies – <sup>3</sup> For anti-asthmatic drugs only

In 2016, sales of reimbursable generics reached € 3,462 million and 898 million units in the retail market...

### Evolution of reimbursable generics' sales in the retail market



Sources: GERS dashboard (December 2016) – Smart Pharma Consulting analyses

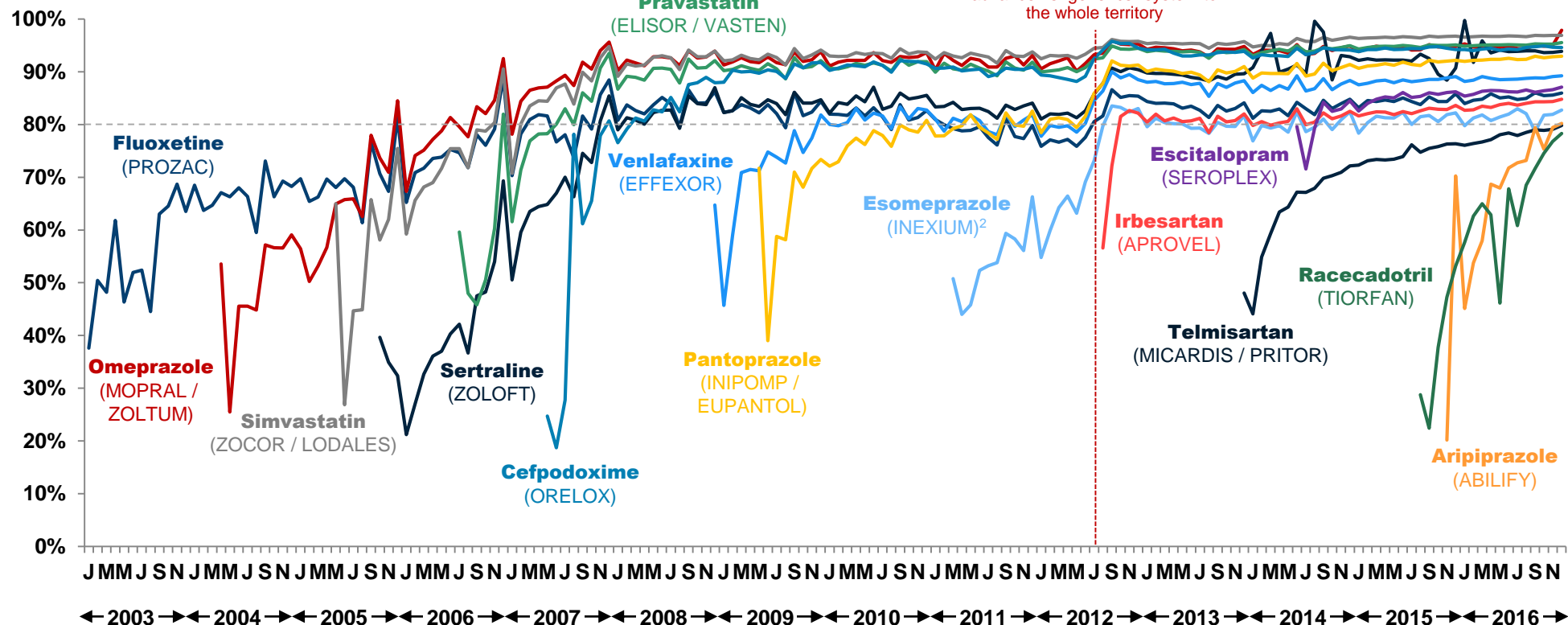
<sup>1</sup> Ex-factory prices

The speed of penetration has accelerated since 2003, reaching ~80% within a few months for brands with no particular difficulties of substitution

## Generics penetration trends on the retail market

Generics penetration for selected high volume drugs

Generics as a % of off-patent units<sup>1</sup>

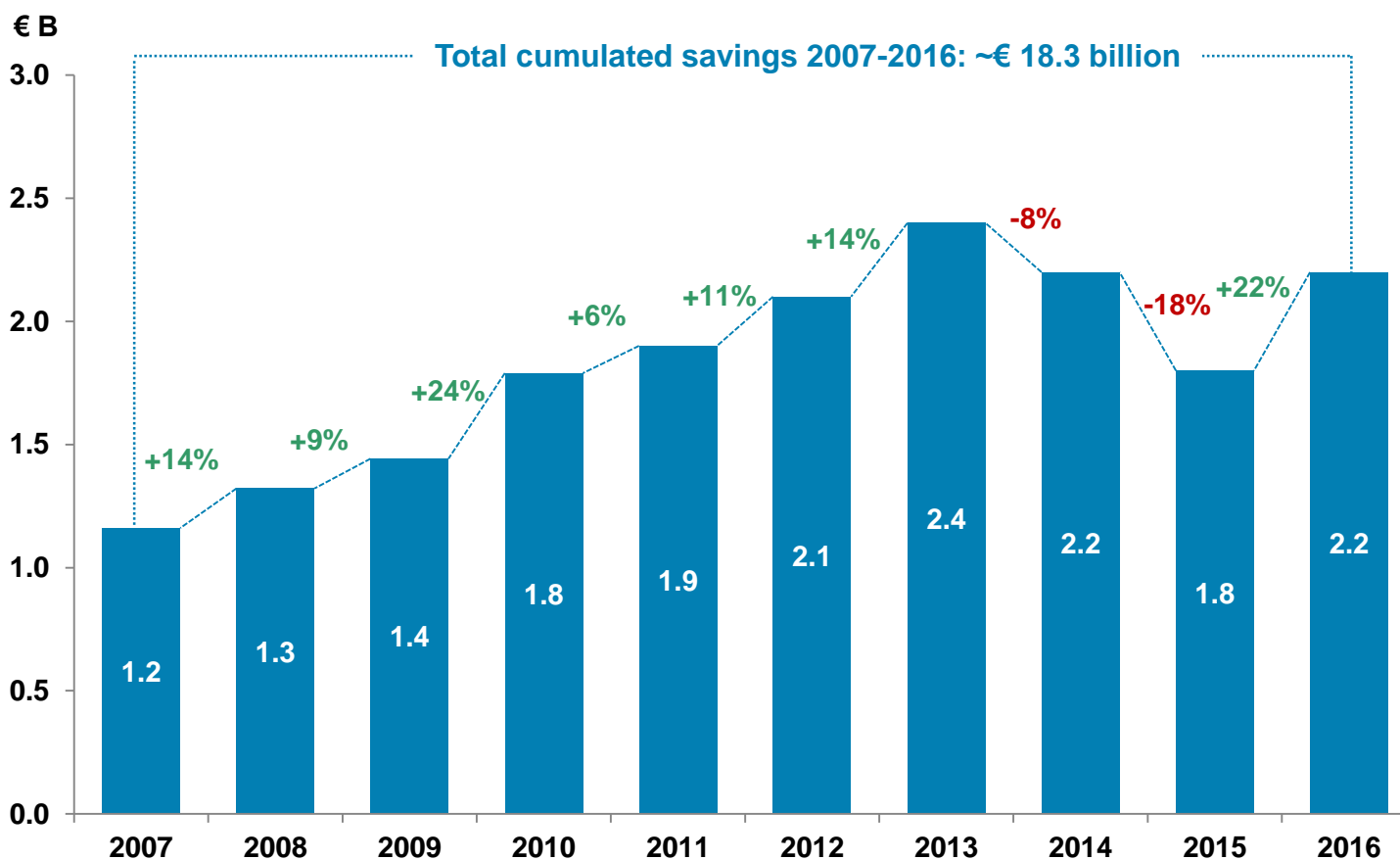


Sources: GERS – Smart Pharma Consulting analyses

<sup>1</sup> Compounded average of the different forms and dosages – <sup>2</sup> Quasi-generics

**Savings generated by the use of generics reached ~€ 2.2 billion in 2016 and accounted for a cumulated ~€ 18.3 billion over the 2007 – 2016 period**

**Savings generated by generics (2007 – 2016)**

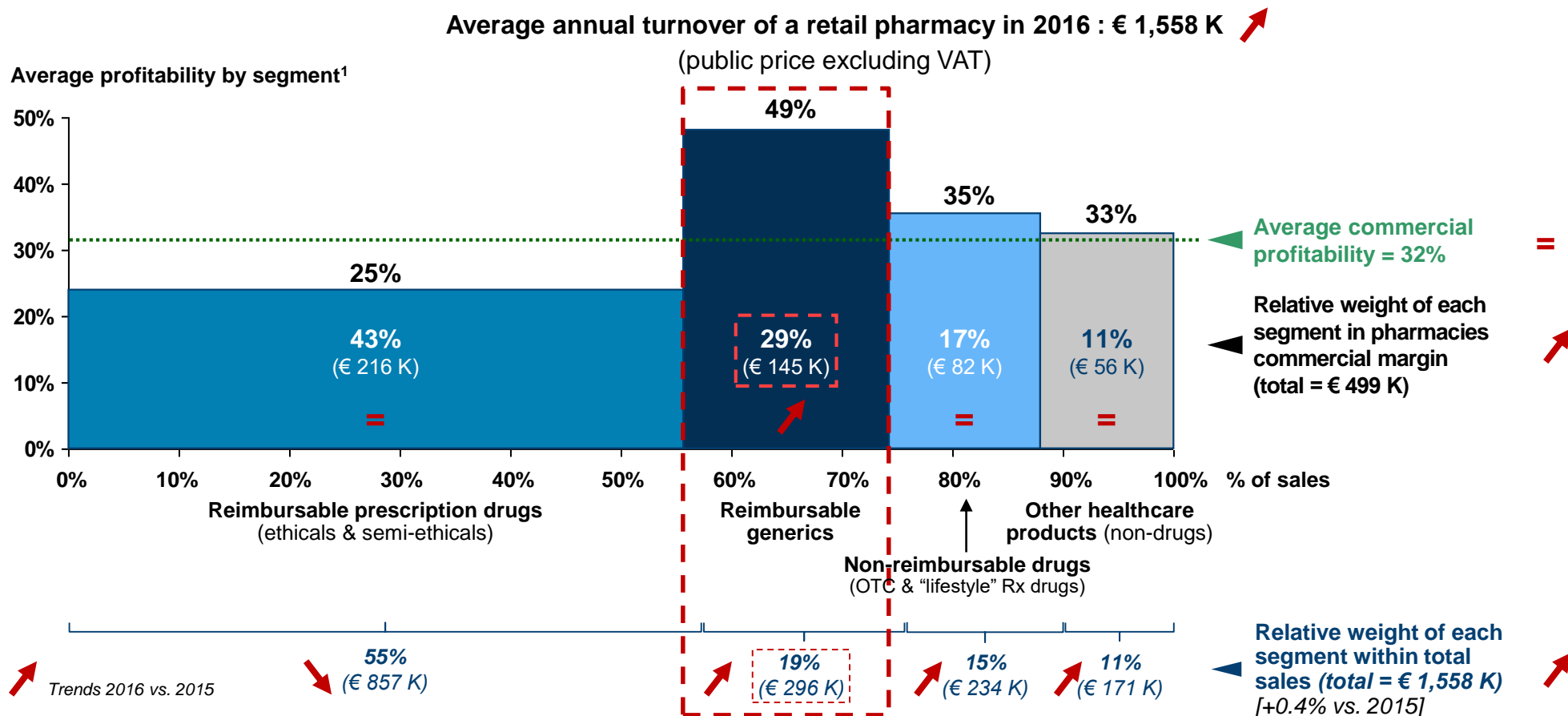


- In 2014, the launch of new generic medicines enabled the market to maintain an **upward dynamic in volume** (+ 2%) and a **fall in value** (-4%) due to price cuts on generics over the period (~ € 220 million)
- Nevertheless, price cuts have impacted even more reimbursable originators, reducing the price differential between originators and generics, and for the first time in 2014, the savings generated by generics decreased (-8%)
- The trend of price cuts in 2015 led to a further decline in savings (-18%) to € 1.8 b, i.e. the level of 2010 but was reversed in 2016 to reach the level of 2014



**In 2016, generics accounted for 19% of retail pharmacies' sales on average, and for 29% of their margin, due to the high rebates offered by generics companies**

**Economic structure of retail pharmacies in France (2016)**



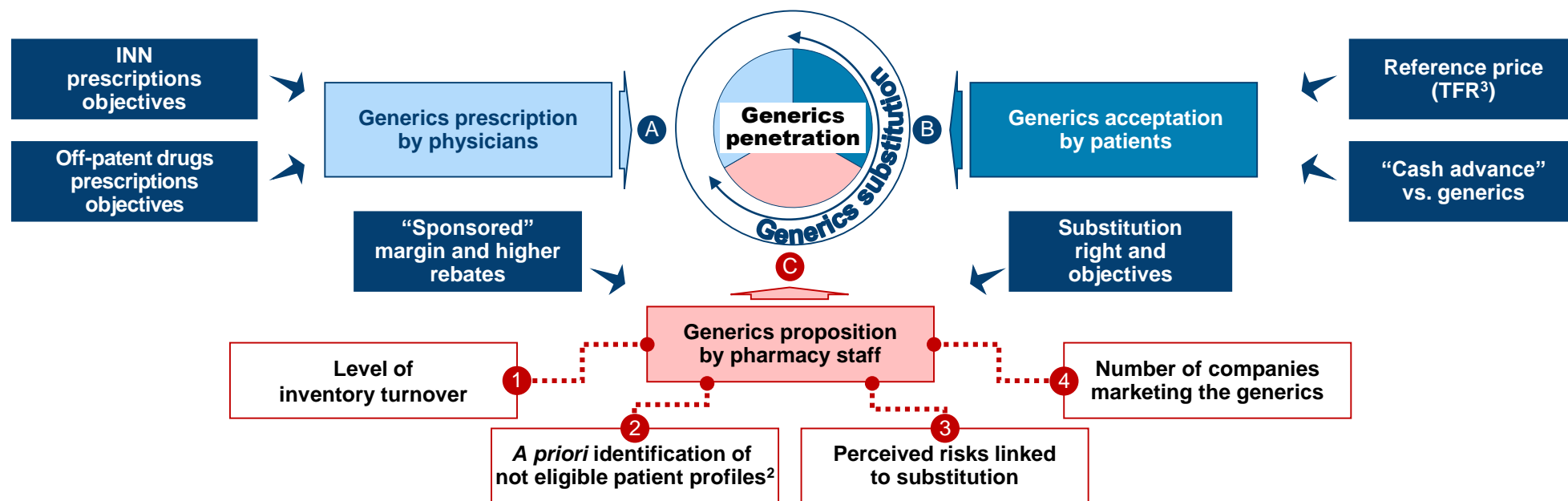
Sources: KPMG (2016) – Smart Pharma Consulting analyses

<sup>1</sup> Inclusive of legal margin, rebates, commercial agreements and remuneration for pharmaceutical services, notably those corresponding to the public health objectives (e.g. generics substitution objectives, pharmaceutical interviews with patients, etc.)

Generics penetration is facilitated by INN<sup>1</sup> prescription and substitution, both of which are enhanced by a favorable support from health authorities

### Key drivers of generics penetration on the retail market

Health authorities measures supporting generics penetration



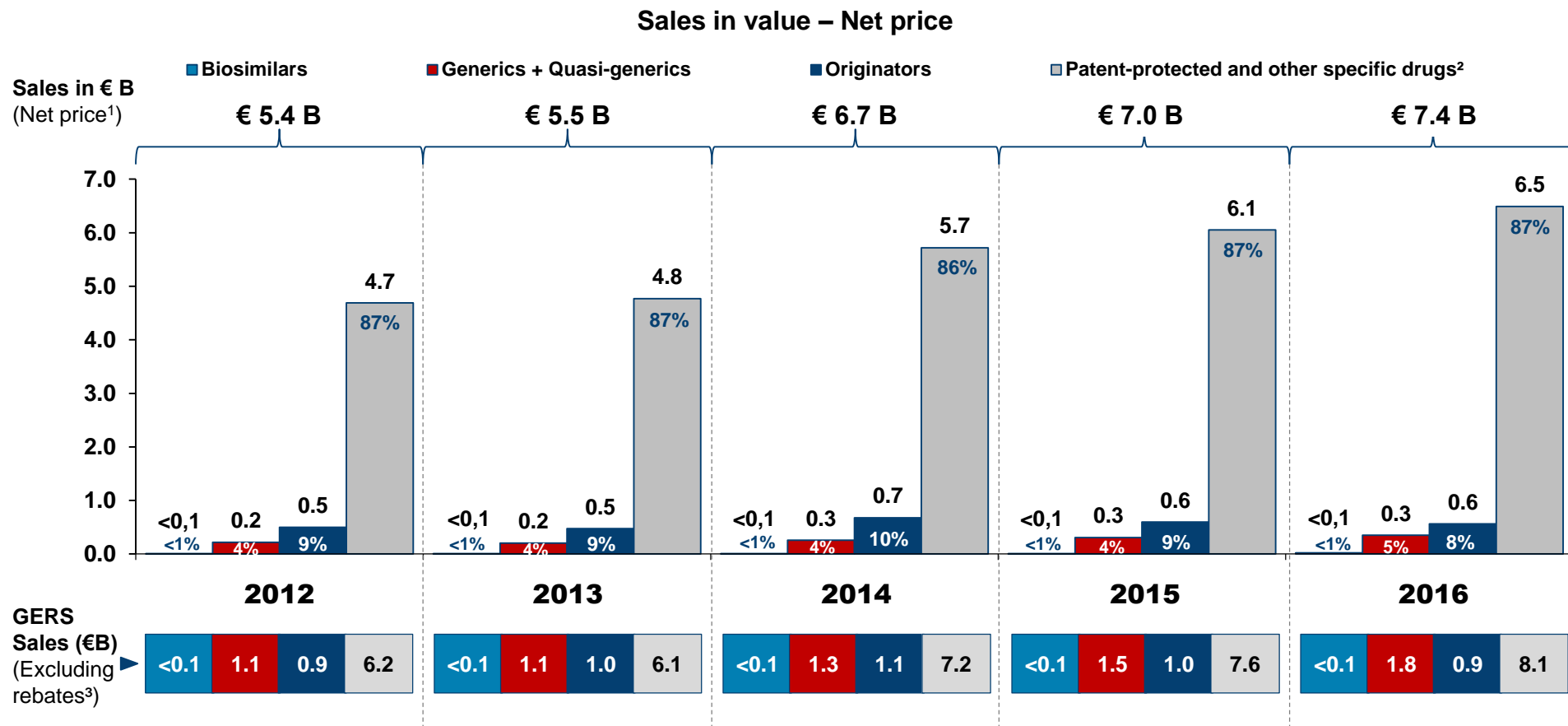
Measures introduced by Health authorities

Sources: Smart Pharma Consulting analyses

<sup>1</sup> International non-proprietary name – <sup>2</sup> To whom substitution will not be proposed (e.g. patients having refused substitution several times) – <sup>3</sup> “Tarif forfaitaire de responsabilité”: single reimbursement price for a generic group as a whole, based on the cheapest generic price

The share of generics in the hospital market in value weights for 4-5% and has been relatively stable since 2012

**Hospital market dynamics**








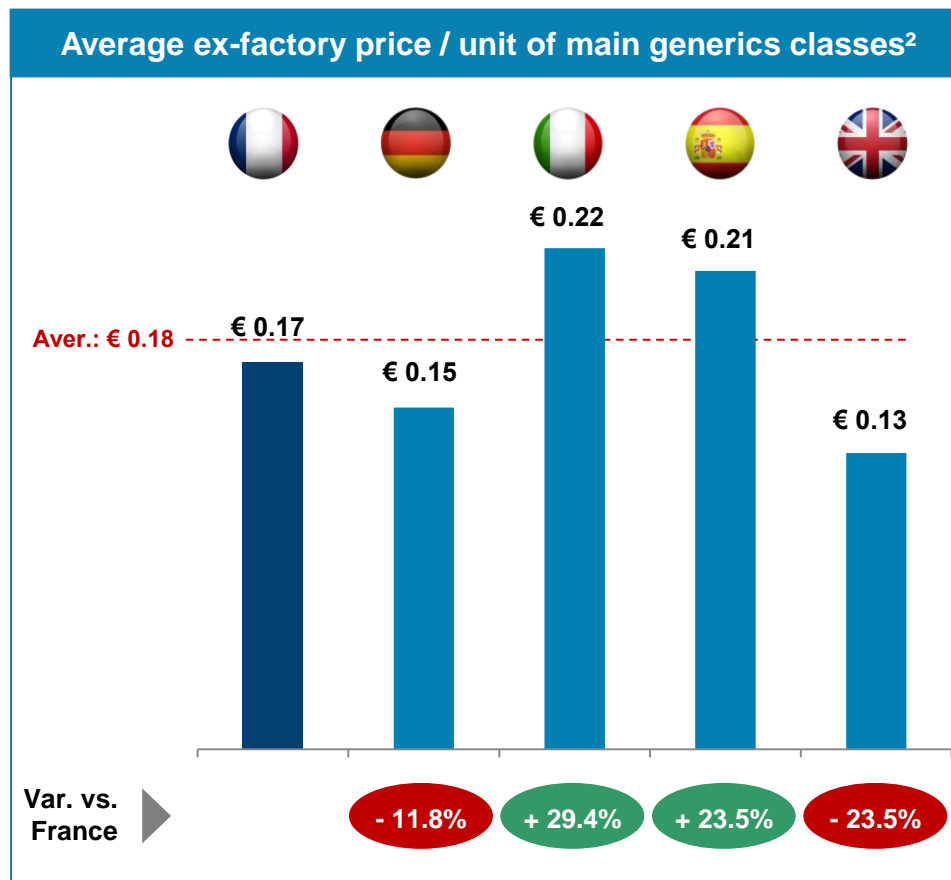
Sources: GERS – Smart Pharma Consulting analyses

<sup>1</sup> Net sales estimated based on GERS sales on which theoretical discounts have been applied: 20% for patent-protected and other specific drugs, 40% for originators and 80% for generics and biosimilars – <sup>2</sup> Drugs not listed in the ANSM generics Directory, including particular products (calcium, sodium, morphine, etc.) – <sup>3</sup> GERS price excluding taxes and rebates

**With an average price of generics of € 0.17 per standard unit, France is now on average with its European neighbors**

### Comparative study of generics prices – Overall result

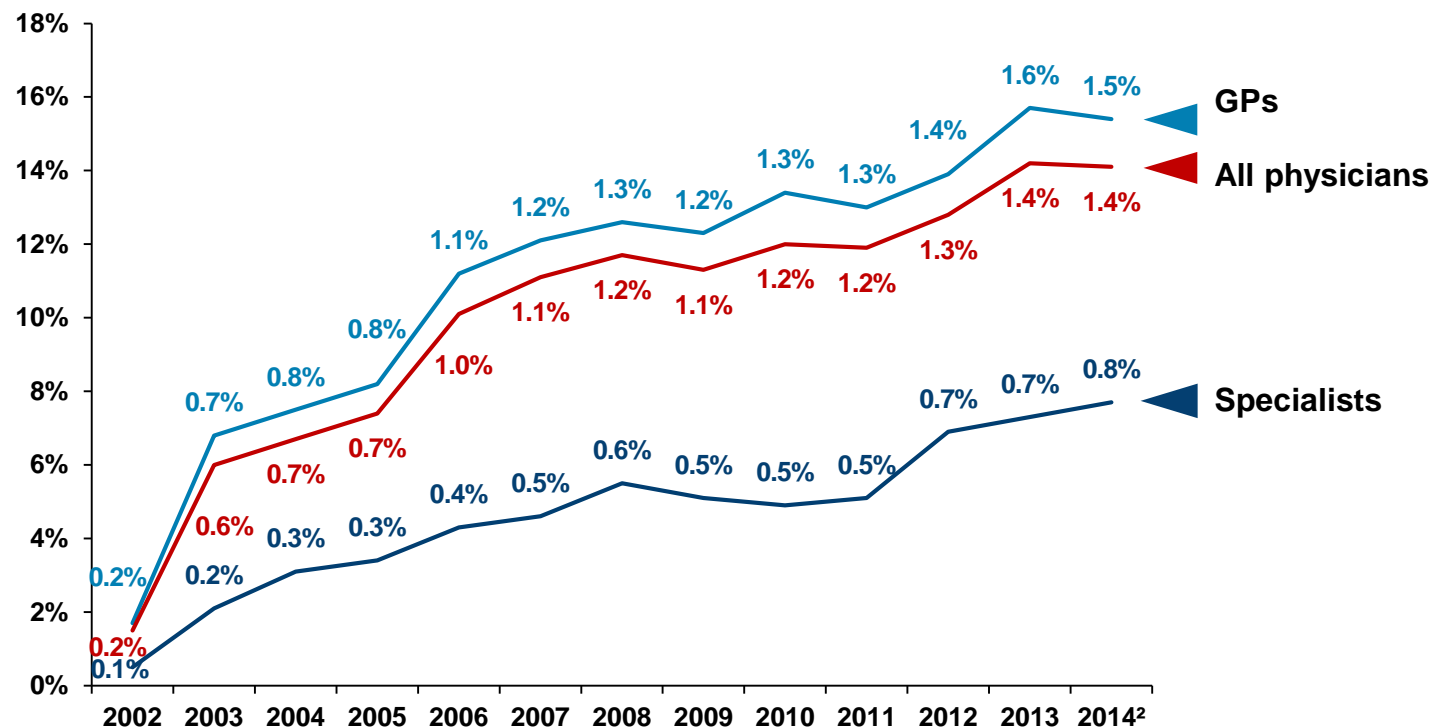
Scope of the study	
Studied reference countries	<ul style="list-style-type: none"> <li>Germany </li> <li>Spain </li> <li>France </li> <li>Italy </li> <li>United Kingdom </li> </ul>
Studied generics classes	<ul style="list-style-type: none"> <li>4 studied classes: statins, proton pump inhibitors (PPI), angiotensin-converting enzyme (ACE) inhibitors and sartans</li> <li>In 2014, these classes represented a turnover of € 735 M in France, i.e. 21% of the generics market</li> </ul>
Selected samples	<ul style="list-style-type: none"> <li>Generics marketed in retail</li> </ul>
Data sources used	<ul style="list-style-type: none"> <li>For France, the data come from the GERS and the price base of the CEPS (taking into account the price cuts achieved in 2015)</li> <li>For the 4 other reference countries, the 2014 data come from the IMS MIDAS database (price data)</li> </ul>
Unit of measure used	<ul style="list-style-type: none"> <li>The unit of measure of the price is the average ex-factory price (in standard unit) charged in a country weighted by the French units in order to neutralize the structural effects</li> </ul>



Since physicians' INN<sup>1</sup> prescription rates are relatively low, generics penetration is mainly due to substitution in retail pharmacies

### Evolution of the INN<sup>1</sup> prescription rate (2002-2014)

As a % of prescriptions



#### Mesures affecting INN prescriptions

- **LFSS 2009** : imposes physicians to mention the INN for generic drugs prescriptions (measure not well respected)
- **Medical agreement signed with the National Health Insurance, July 2011**: provides a remuneration based on physicians' performance on, among other things, generics prescription objectives
- **“Bertrand law”, December 2011**: stipulates that all the prescriptions must mention the INN from January 2015. However, the prescription can be supplemented by the brand name
- **2015** : Mandatory INN prescription

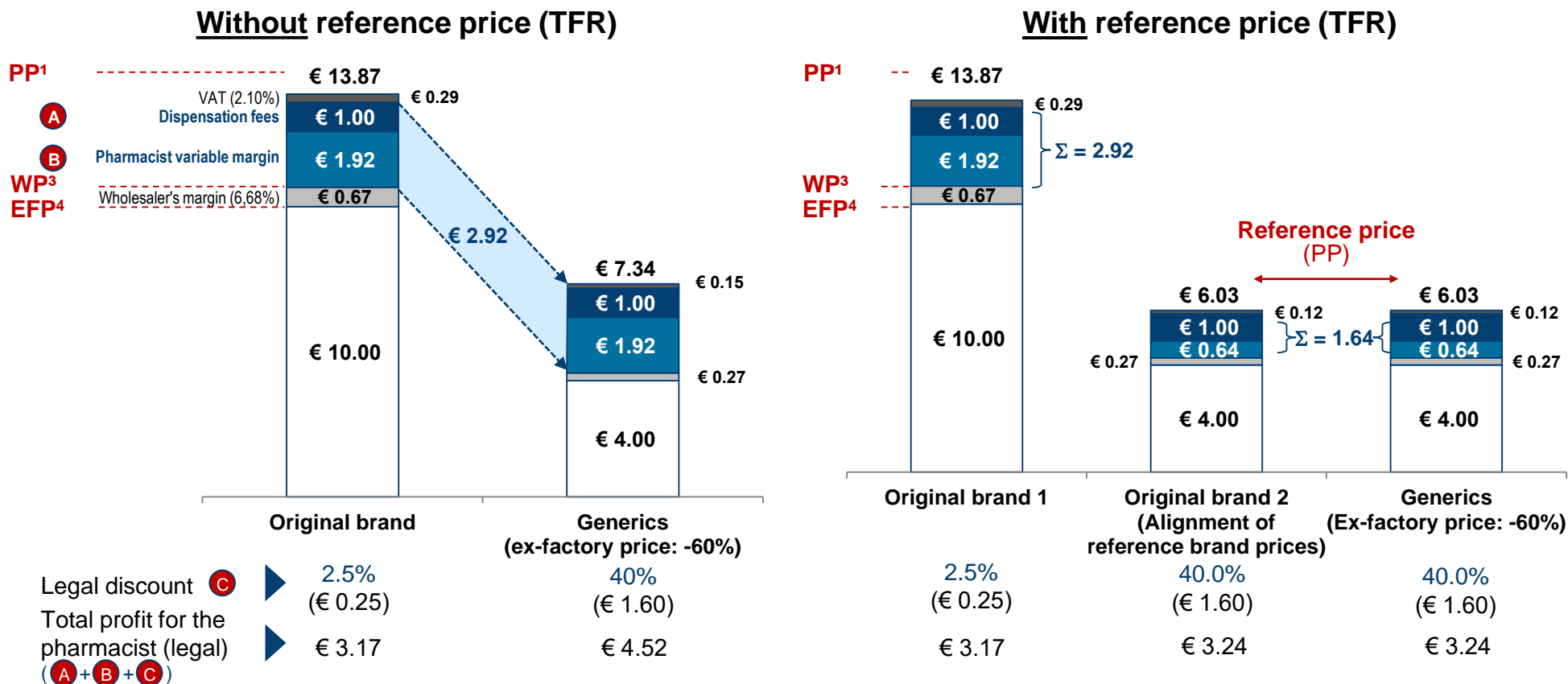
Sources: “Baromètre de la prescription en DCI”, Mutualité française based on IMS data – Smart Pharma Consulting analyses

<sup>1</sup> International non-proprietary name, without associated brand name

<sup>2</sup> Moving Annual Total as of August 2014 (No update since)

The levels of margins and rebates set by the CEPS for drugs sold on the retail market contribute to regulate the evolution of cost of reimbursed drugs

**Legal margins and discounts for reimbursed generics (2018)**

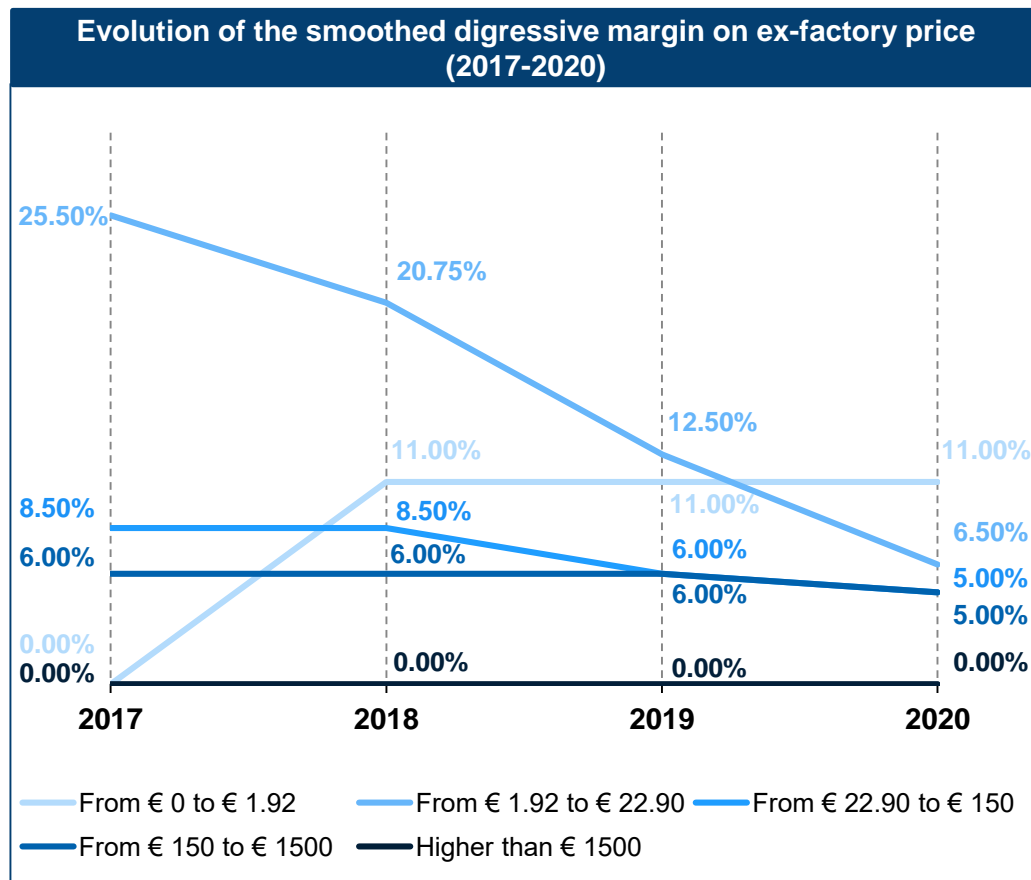


Sources: Smart Pharma Consulting analyses

<sup>1</sup> Public price, incl. taxes and dispensing fees – <sup>2</sup> Dispensing fee as applicable since January 1<sup>st</sup>, 2016, i.e. € 1.02 incl. taxes – <sup>3</sup> Wholesaler price, excl. taxes – <sup>4</sup> Ex-factory price, excl. taxes

## The 11<sup>th</sup> amendment to the National Pharmaceutical Agreement provides for reducing margin on ex-factory price of drugs over the 2018-2020 period for pharmacists

### The 11<sup>th</sup> amendement to the National Pharmaceutical Agreement



- The main priority of the 11<sup>th</sup> amendment<sup>1</sup> to the National Pharmaceutical Agreement is to change the remuneration of pharmacies and make them **less dependent on the price and volume of reimbursable drugs**
- Thus, it proposes **progressive transfer** of a significant part of the regulated margin on the price of medicines to **new forms of remuneration** related to dispensing and to the improvement of patients' management
- Thus, three successive waves of **margins** on price **decreases** are expected in January of each year from 2018 to 2020
- The creation of **3 new dispensing fees** will only be settled from 2019 and only 2 of the 3 fees are expected to be re-evaluated in 2020:

New dispensing fee	2019 <sup>2</sup>	2020 <sup>2</sup>
Fees for the delivery of a prescription	€ 0.51	€ 0.51
Fees related to the age of the patient (youth children and elderly people)	€ 0.51	€ 1.58
Fees for the delivery of specific drugs (e.g. immunosuppressive drugs)	€ 2.04	€ 3.57

Sources: Le moniteur des pharmacies, August 26<sup>th</sup>, 2017 – 11<sup>th</sup> amendment to the National Pharmaceutical Agreement

<sup>1</sup> The 11<sup>th</sup> amendment was signed on July 20<sup>th</sup>, 2017 by only one of the three French pharmaceutical unions – <sup>2</sup> All taxes included

The resistance of some drugs to generics substitution can be explained by several factors such as the complexity of the pathology and the narrow therapeutic margin

### Main limiters of substitution for selected drugs

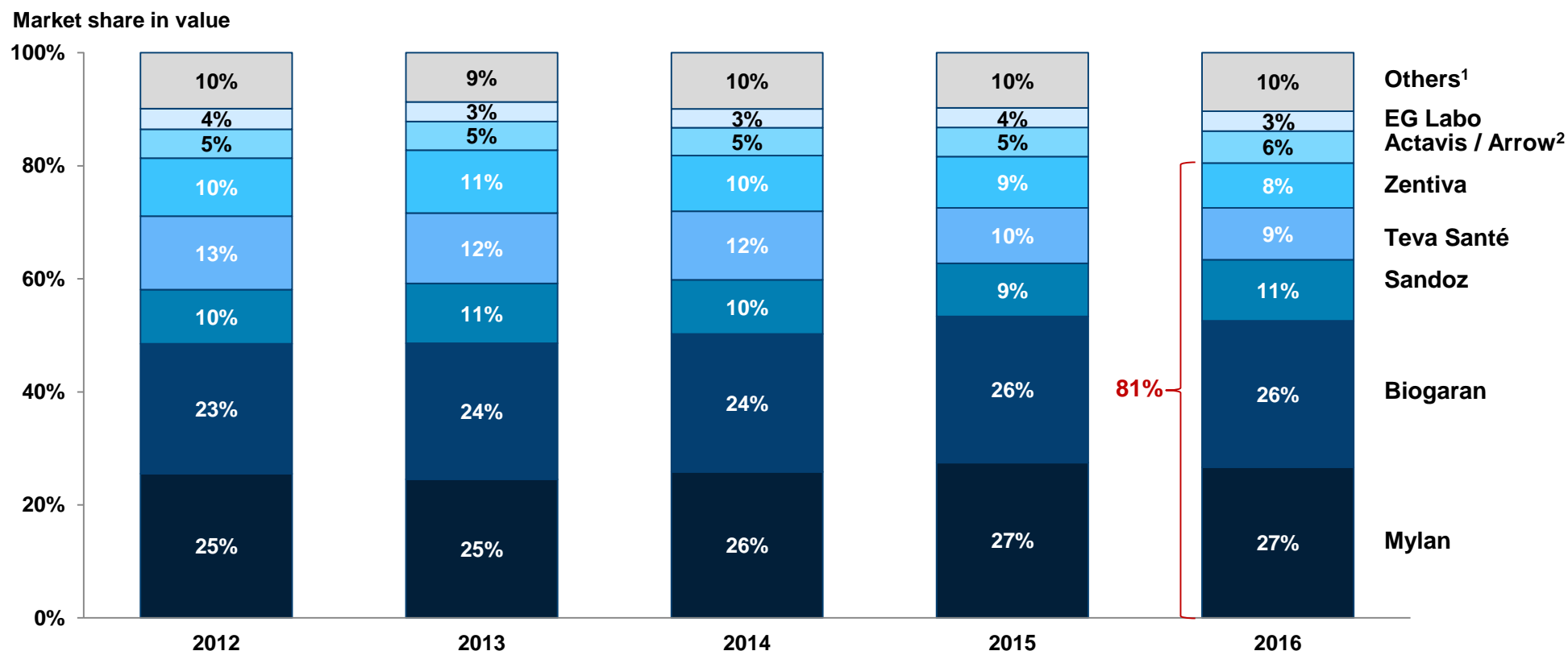
	Complexity / Severity of pathology	Narrow therapeutic margin	Low inventory rotations	Frequent “not substitutable” scrips	Difference of chemical forms in comparison with generics	Protection of an indication
<b>Durogesic</b> (fentanyl)	✓	✓	✓			
<b>Levothyrox</b> (levothyroxine)	✓	✓				
<b>Epitomax</b> (topiramate)	✓			✓		
<b>Neurontin</b> (gabapentin)	✓			✓		
<b>Plavix</b> (clopidogrel)				✓	✓	✓
<b>Risperdal</b> (risperidone)	✓			✓		

- For those drugs with specific conditions, in order to limit prosecutions engaging their responsibility, pharmacists tend to:
  - Follow the ANSM<sup>1</sup> recommendations regarding narrow therapeutic margins
  - Respect generic groups as defined in the ANSM Directory
  - Respect substitution rules regarding protected indications (protection of intellectual property)



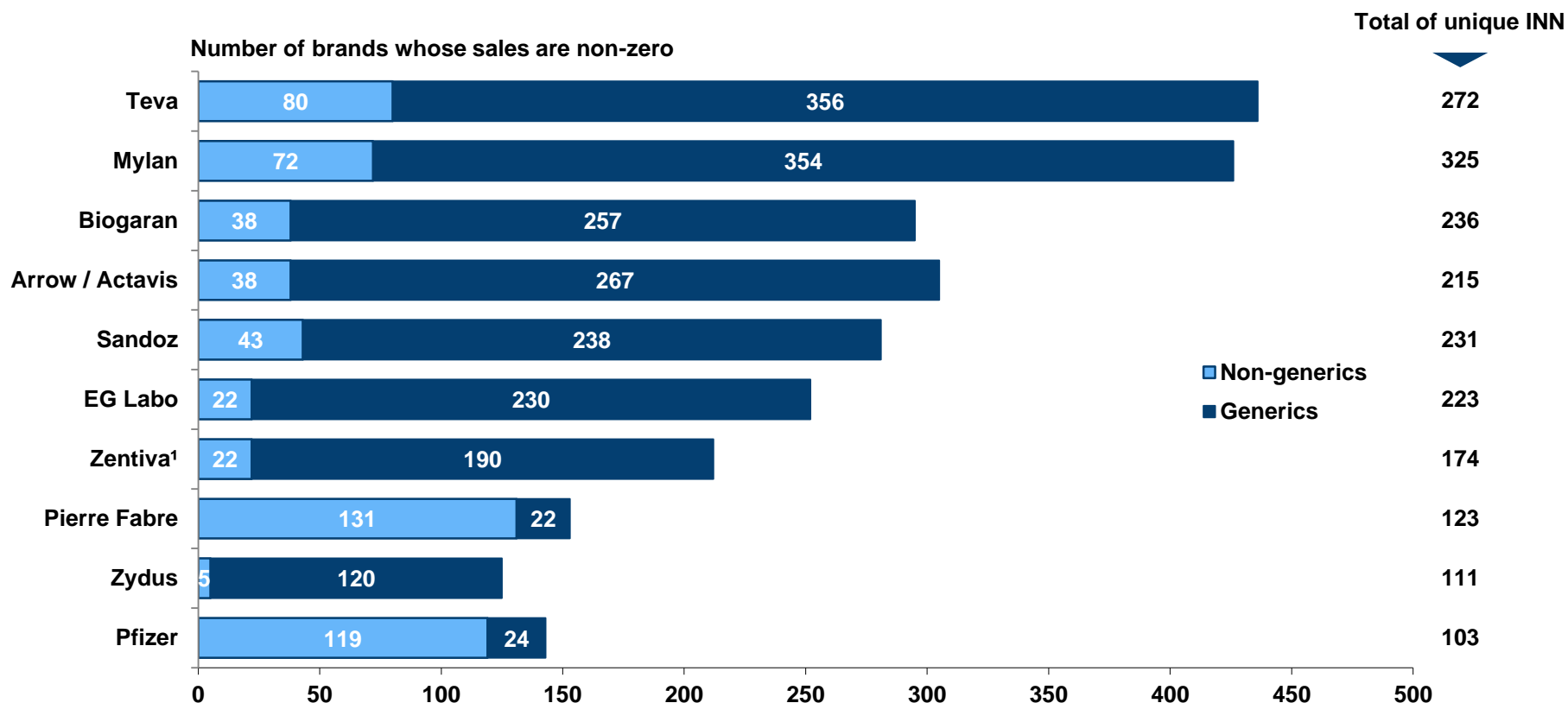
The French generics market is concentrated with 81% of the sales captured by the top 5 players, whose market shares are relatively stable

**Market share of generics companies in the retail market (2012 – 2016)**



The scope of the portfolio proposed by the generics companies is a determining factor in their referencing with retail pharmacies

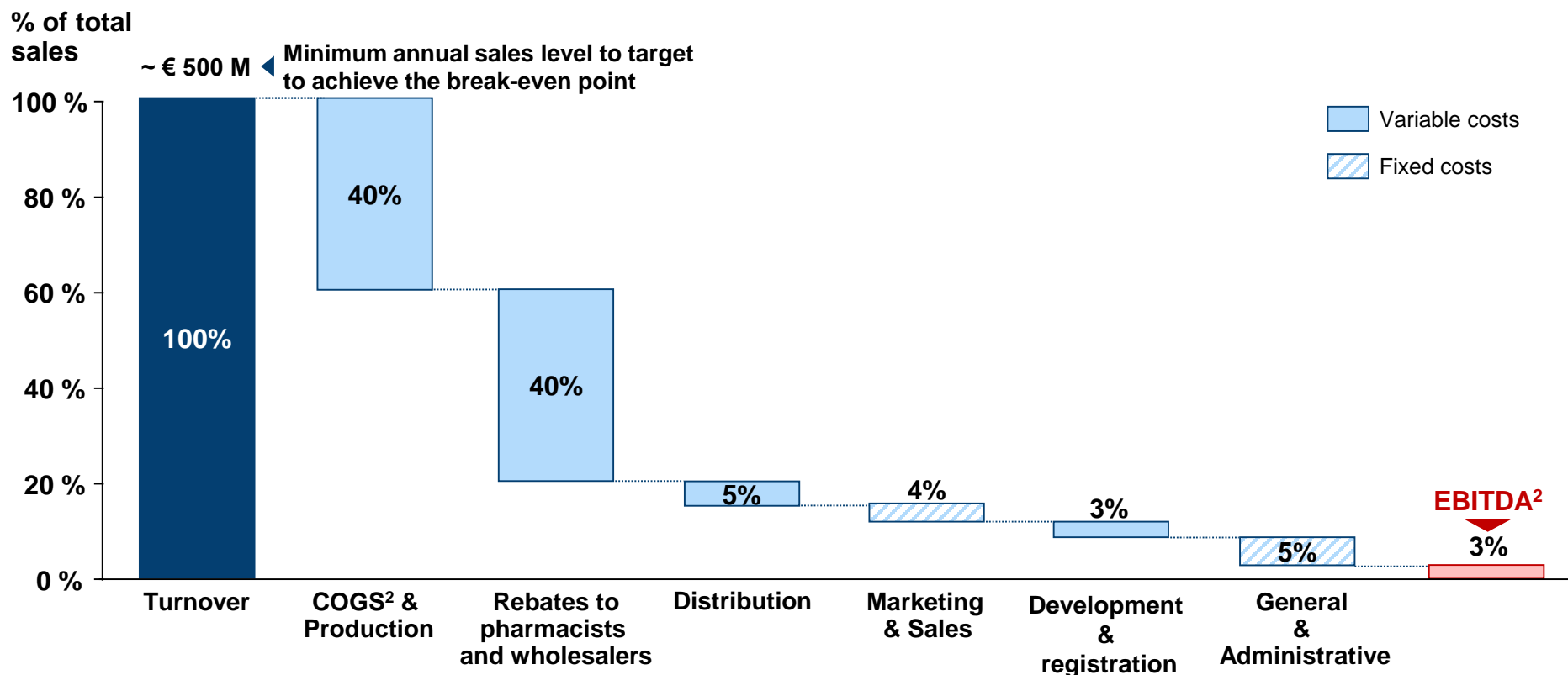
### Product portfolio of generics companies in retail pharmacies (2016)



Notes: The ANSM Directory contains 483 different INNs in December 2016  
Some INNs may be registered as generic or non-generic depending on the presentation (dosage, packaging, form)

The average turnover to generate operating profitability (EBITDA<sup>1</sup>) is estimated at ~ € 500 M for generics companies operating in the retail market

**Estimated cost structure of generics companies in France**





### Key data for the French affiliate

#### Key financial data (2012-2016)<sup>1</sup>

€ million	2016	2015	2014	2013	2012
Turnover	838	780	867	936	872
EBITDA/Turnover	10.5%	6.1%	9.1%	8.3%	5.5%
EBIT/Turnover	9.6%	5.6%	8.3%	7.1%	4.9%
Net result/Turnover	7.1%	4.6%	6.3%	5.8%	4.6%

#### Sales data (2016)<sup>2,3</sup>

	Sales (€ million)	YoY change	Share of turnover
Generics	1,594	+4.9%	86.6%
Quasi-generics	30	+5.2%	1.6%
Biosimilars	0	N/A	N/A
Principes	218	+11.7%	11.8%
<b>Total</b>	<b>1,842</b>	<b>+5.7%</b>	<b>100.0%</b>

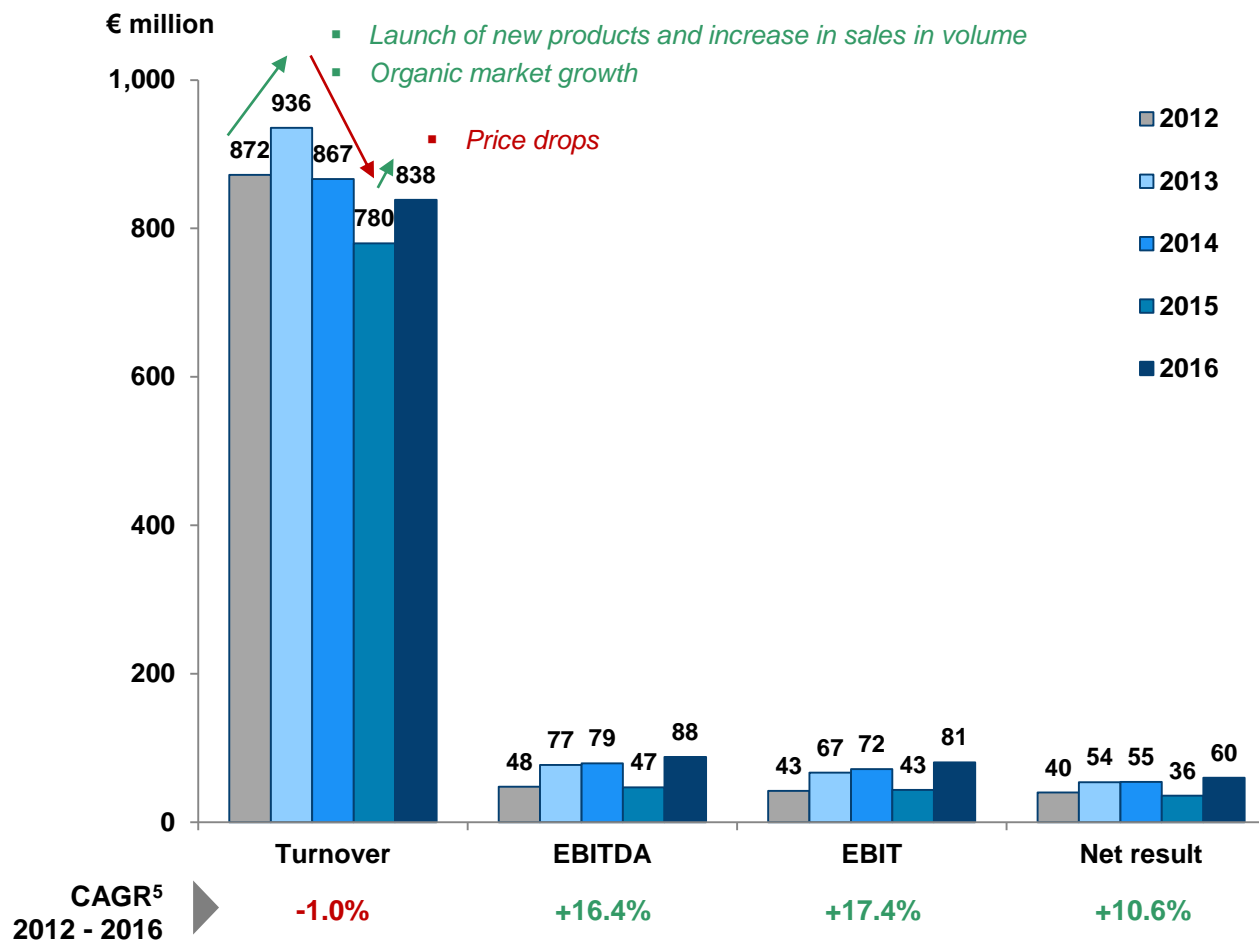
#### Top 3 generics therapeutic areas<sup>4</sup>

1. Injectable corticosteroids	88	+29.0%	4.8%
2. Proton pump inhibitors	71	+9.3%	3.9%
3. Non-narcotics & anti-pyretics	67	+0.4%	3.6%

#### Field team

~ 100 pharma reps

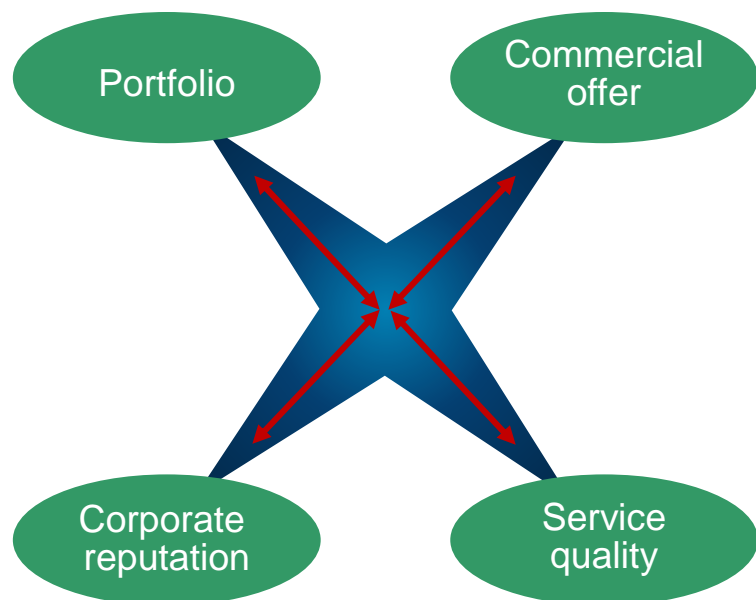
### Profitability analysis (2012-2016)<sup>1</sup>



**The Generics Preference Mix allows generics companies to identify and evaluate the drivers of pharmacists' preference at the time of listing and handing out generics**

**Generic Preference Mix : Description**

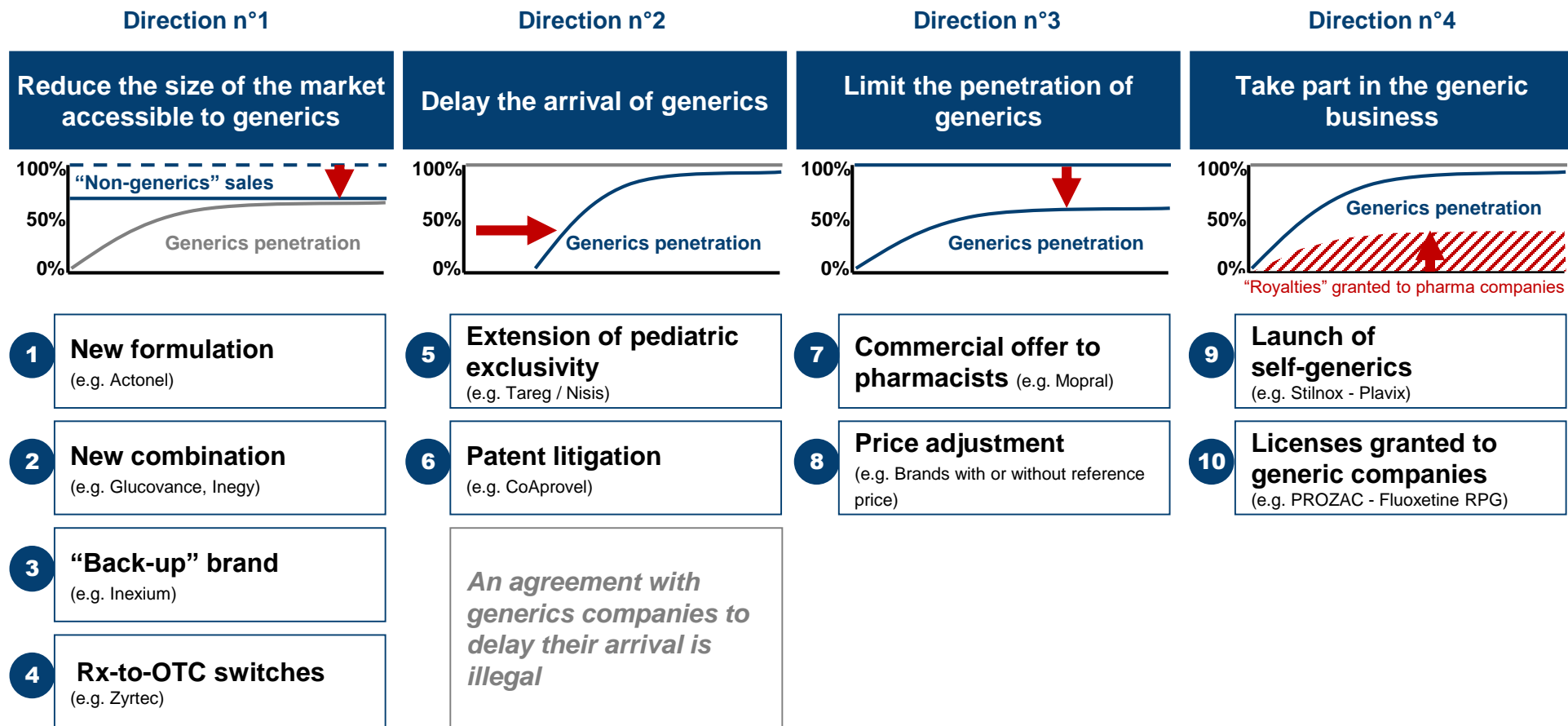
**The 4 components of the  
Generic Preference Mix**



- The *Generics Preference Mix* (GPM) has been developed by Smart Pharma Consulting
- To the extent that retail pharmacists generally focus the great majority of their generics orders on a single supplier and that they have an increasingly important role through counseling and the right of substitution ...
- ... it is essential for generics companies to increase the preference of pharmacists for their brands
- To develop and strengthen pharmacists' preference for their products, generics companies must seek to optimize their *Generics Preference Mix*, which relies on pharmacists' perception of:
  - The breadth and quality of their product portfolio
  - The attractiveness of their commercial offer
  - The quality and the interest of their offered services
  - Their reputation
- The links between the 4 components of *the Generics Preference Mix* should be well established in the minds of clients

Pharma companies can follow 4 directions and use 10 strategic levers to protect the value of their brand despite the arrival of generics

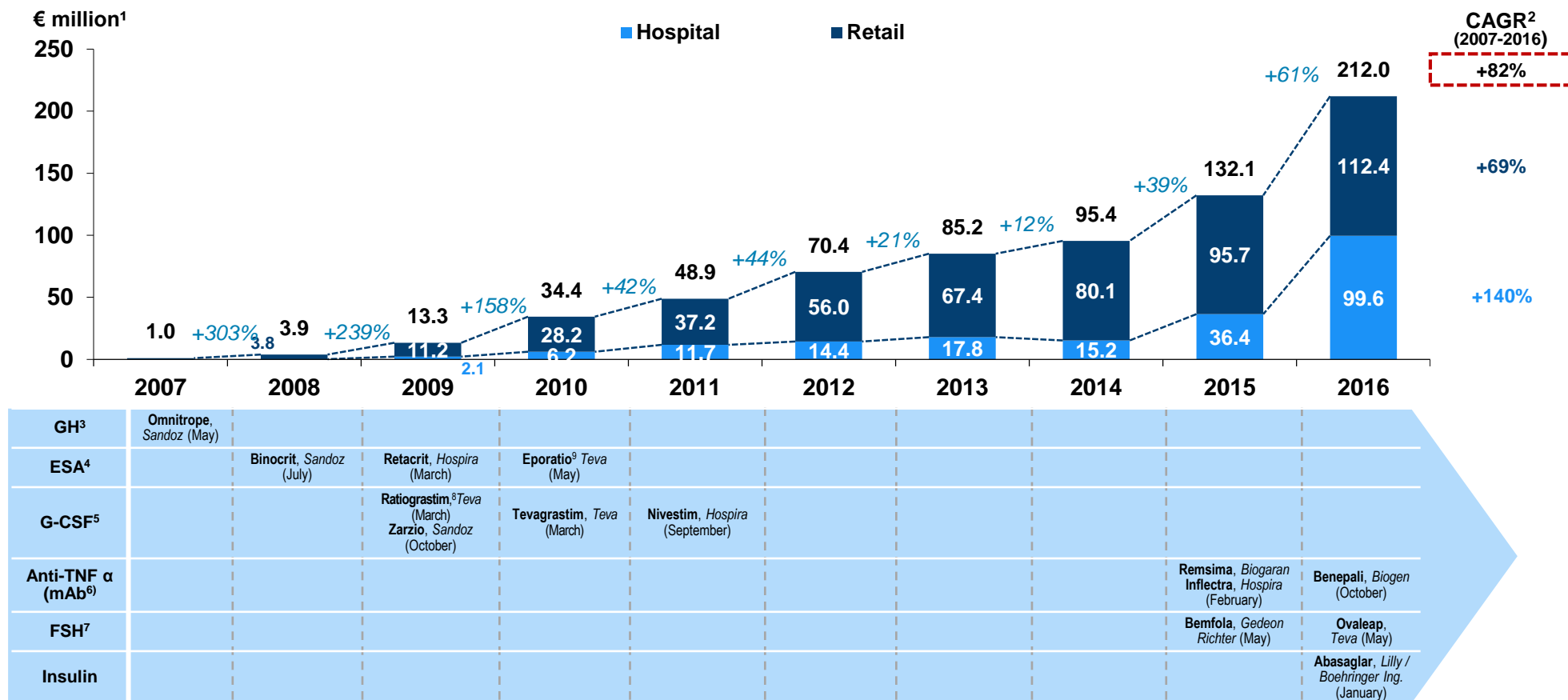
**Strategic options of the pharma companies**



Sources: Smart Pharma Consulting analyses

Sales of biosimilars, which were launched in 2007 and belonged to six types of products in 2016, reached a total ~ € 212 million on the total market in 2016

### Evolution of the biosimilars market (2007 – 2016)

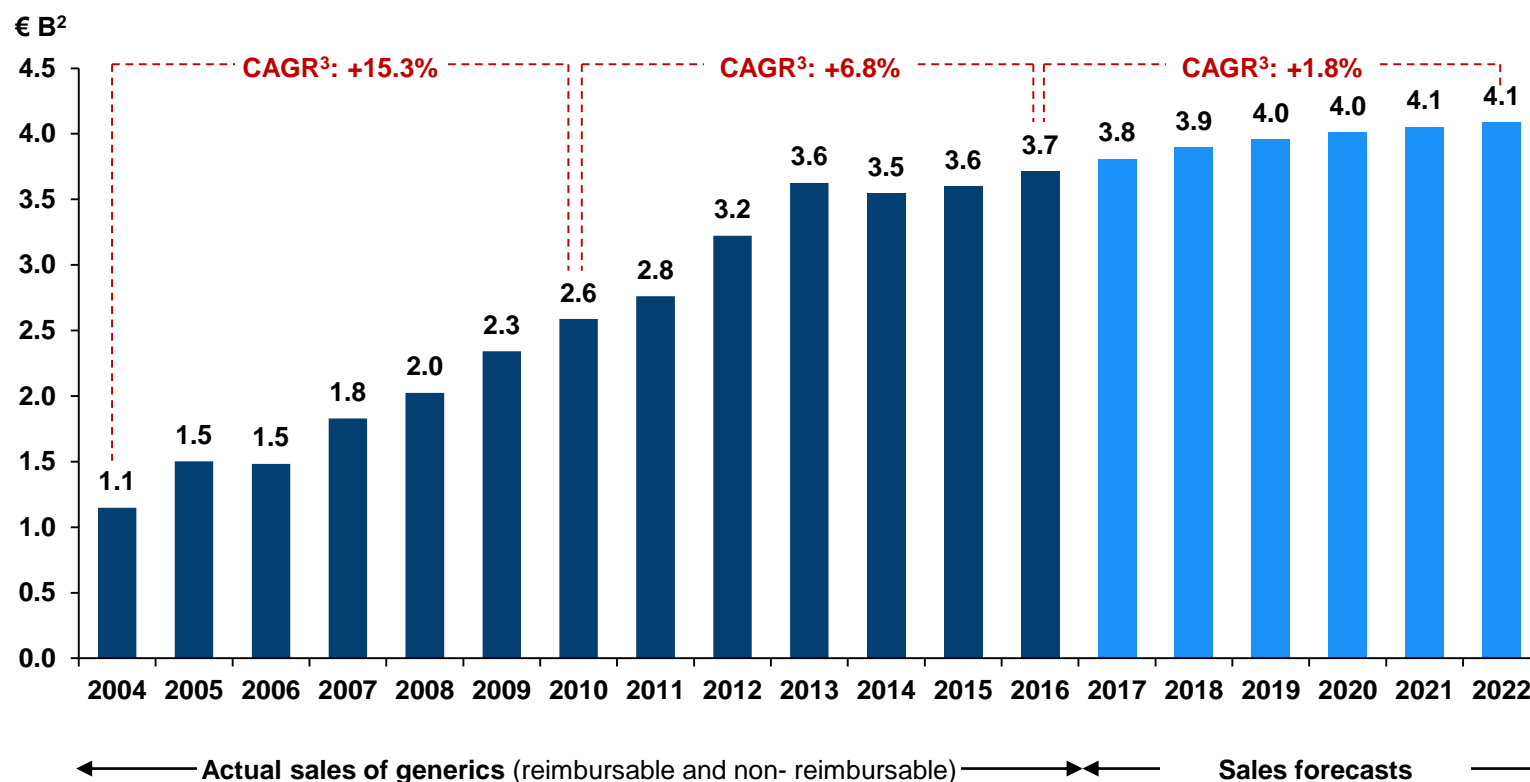


Sources: GERS – Smart Pharma Consulting analyses

<sup>1</sup> Ex-factory prices excluding rebates – <sup>2</sup> Compound annual growth rate – <sup>3</sup> GH: Growth hormones – <sup>4</sup> ESA: Erythropoiesis stimulating agents – <sup>5</sup> G-CSF: Granulocyte colony stimulating factors – <sup>6</sup> mAb: Monoclonal antibodies – <sup>7</sup> FSH: Follicle Stimulating Hormone – <sup>8</sup> Ratiograstim was removed from market in 2016 – <sup>9</sup> Eporatio is not a biosimilar per se but is rather a « me-too » product. It was first launched by Ratiopharm, before to be acquired by Teva in March 2010

The average annual growth in value of the generics retail market is expected to remain below 2% by 2020, in particular as a result of price cuts

### Forecasts of generics sales<sup>1</sup> in the retail market – Value



#### Comments

- The low CAGR in value, estimated at 1.8% between 2016 and 2022 can be explained by two factors:
  1. The number of molecules with high potential for the generics market that will lose their patents during the period will be relatively limited
  2. The authorities will continue to regularly impose drastic price cuts



## Authorities and payers will continue to lower the prices of reimbursed drugs, generics or non-generics, and promote the use of generics

### 1 Position of health authorities and payers

#### 2017 – 2022 Trends

##### Optimization

- New initiatives to stimulate generics growth
  - Substitution of inhaled drugs<sup>1,3</sup> and biosimilars<sup>2,3</sup>
  - Extension of the generic Directory to inhaled respiratory drugs as well as for drugs of plant or mineral origin
  - Prescription objectives within the generics Directory at hospital
  - Simplification of generics instruction and notification processes
  - Prioritization of the generics' dossier instruction
- Continuous price pressure in reimbursed drugs, originators and generics (price cut, reference prices (TFR<sup>4</sup>))
- Toughening of reimbursement and price attribution rules for originators (e.g. comparative studies, medico-economics data)



#### Rationale

- The “pact of responsibility”, launched in January 2014, foresees savings of € 3.5 billion over the period 2015 - 2017 due to lower drug prices and the development of generics. However, generics will also be subject to price cuts, tariff convergences with originators and new TFRs
- Health expenditure objectives set by the government at an average of + 2.0% per year by 2020
- Drugs accounted for only 17.4% of healthcare expenditure in 2015, but since price cuts have no negative political and social impact and are easy to implement, they are used as an adjustment variable

##### Quality control of drugs

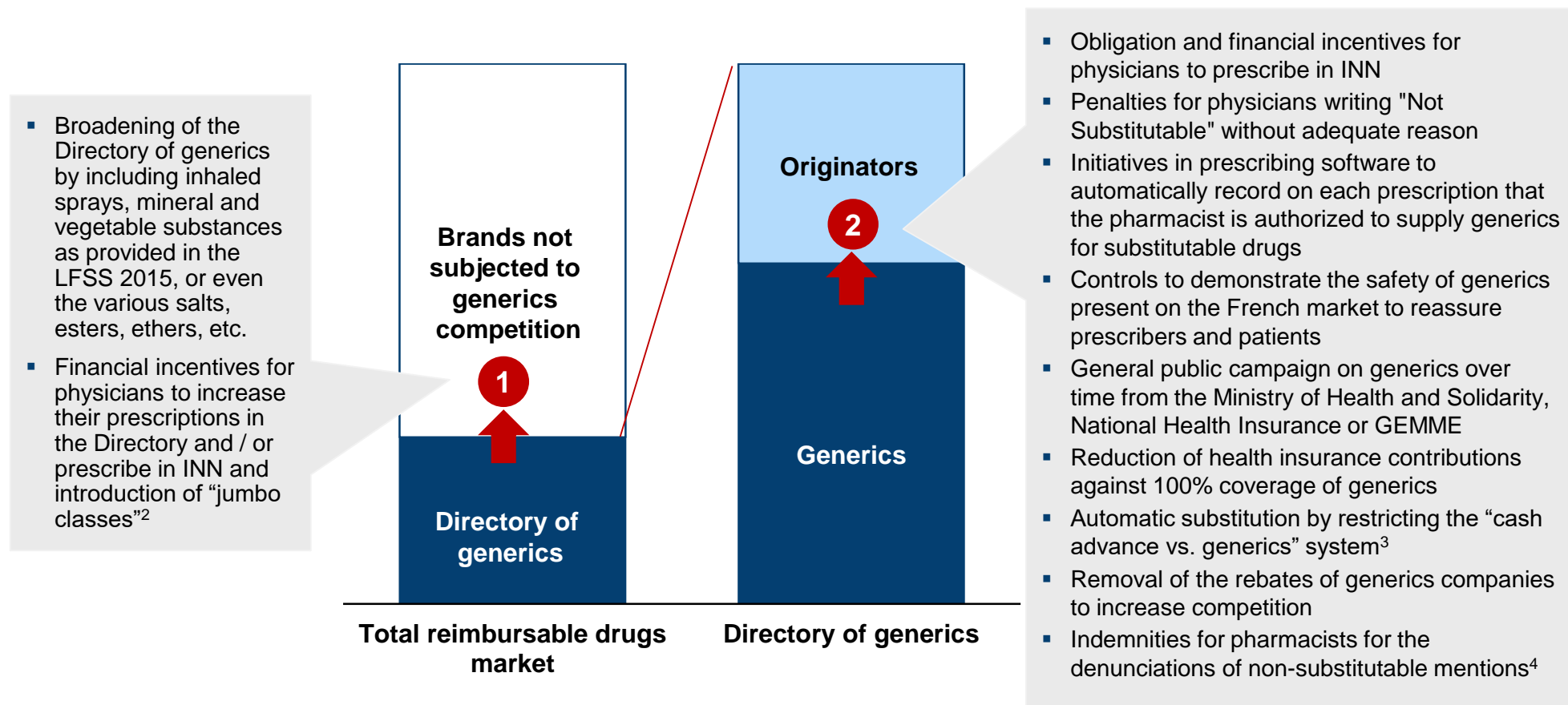
- Control of generics quality, particularly best-selling drugs, in comparison to originators



- The objective is to show the safety of generics present on the French market, these controls being part of the national action plan for the promotion of generics 2015-2017

... these measures follow two distinct axes: the expansion of the Directory of generics and the gain of market shares of generics against originators

**Possible government measures<sup>1</sup> to boost the generic market**





**Be a Smart Manager**

***Not just a ~~Good~~ one!***

**Concepts**

**Methods**

**Tools**

**The Seven tips  
you can't ignore**

Position Paper

June 2017

  
**Smart Pharma  
Consulting**

*"The Smart Manager knows where, why and how to go"*

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**This position paper introduces our concept of Smart Manager, demonstrates its superiority and recommends tips to switch from a Good Manager to a Smart Manager**

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### **Introduction**

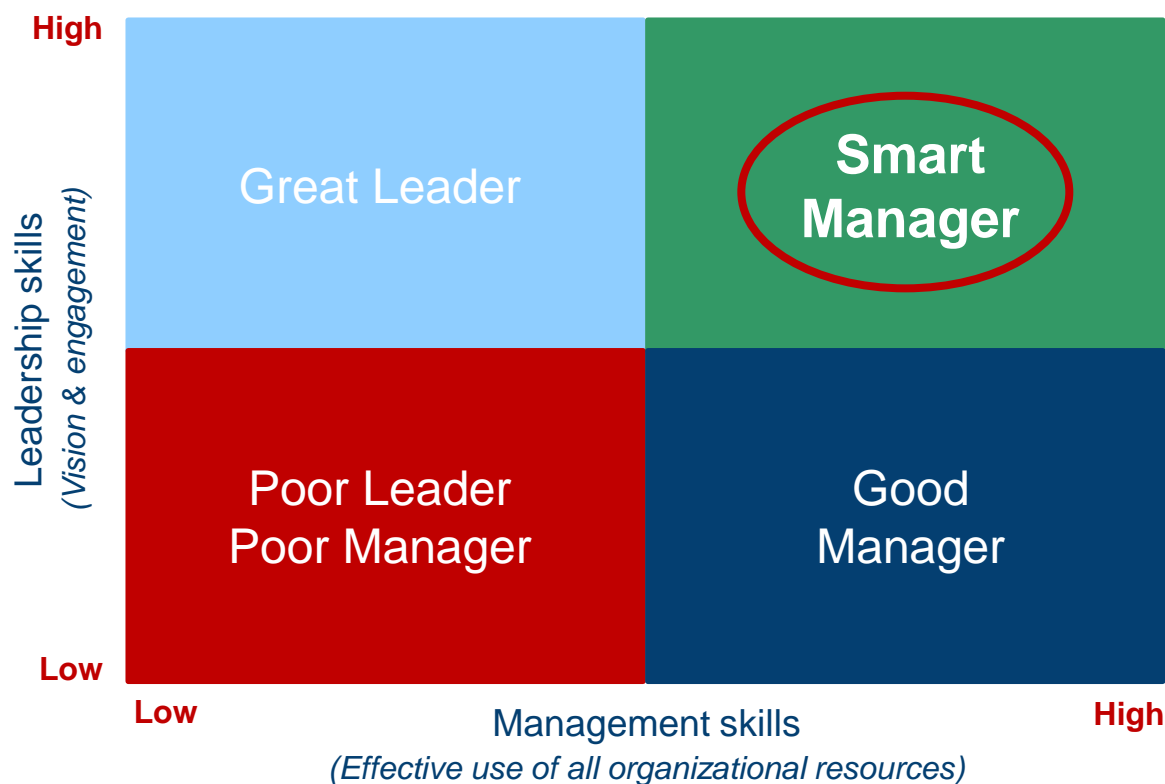
- So many things – often contradictory and rarely applicable – having been said and published about management that it has become **difficult** to **write something new** and **pragmatic**
- Nevertheless, Smart Pharma Consulting has decided to **face the challenge** of:
  - Demonstrating **why** being a **Good Manager** is **not sufficient**...
  - ... and **why** each manager **must strive** to be a **Smart Manager**
  - Proposing **seven tips** to become a **Smart Manager**
- Our **recommendations** are based on **reference articles** and on our **own experience** of consultant and manager
- In this position paper, **we propose concepts, methods** and **tools** amongst which several have been **developed** and **tested** by **Smart Pharma Consulting**

***“Management is the art of getting things done through people” – Mary Parker Follet***

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The Smart Manager is a visionary who has the ability to keep his collaborators engaged and motivated while meeting company's objectives in an efficient manner

**The Manager / Leader matrix**



- **Leaders** show the way to their collaborators by creating and communicating a vision and through their assertiveness. They excel at inspiring and engaging people so that they will strive willingly to reach organizational goals
- **Good Managers** are able to plan, organize and monitor the work of organization members, using all available organizational resources to reach a given organizational goal
- **Smart Managers** combine the skills and competencies of leaders and of good managers. They are also specifically characterized by the following dimensions:
  - High agility of mind to adjust to external and internal changes
  - Perceptual acuity to see change coming
  - Quality of judgment to formulate and select the appropriate solutions
  - Credibility to get decisions accepted by collaborators

---

The Smart Manager, as we define it, is a Good Manager who knows and understands strategic issues in which its actions and its collaborators actions are framed

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**The Smart Manager – Definition**

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**Good Managers**

A good Manager is responsible for  
planning, organizing, directing  
or monitoring the work of  
collaborators, while developing  
them, and taking corrective actions  
when necessary,  
to achieve - in the most efficient  
manner - the objective set

**Smart Managers**

A Smart Manager knows and  
understands the environment, is  
able to contribute to and express  
the purpose, the mission, the vision  
and the values of the company;  
to engage his collaborators, give a  
meaning to their actions and frame  
them within a clear strategy  
to achieve the shared objective set

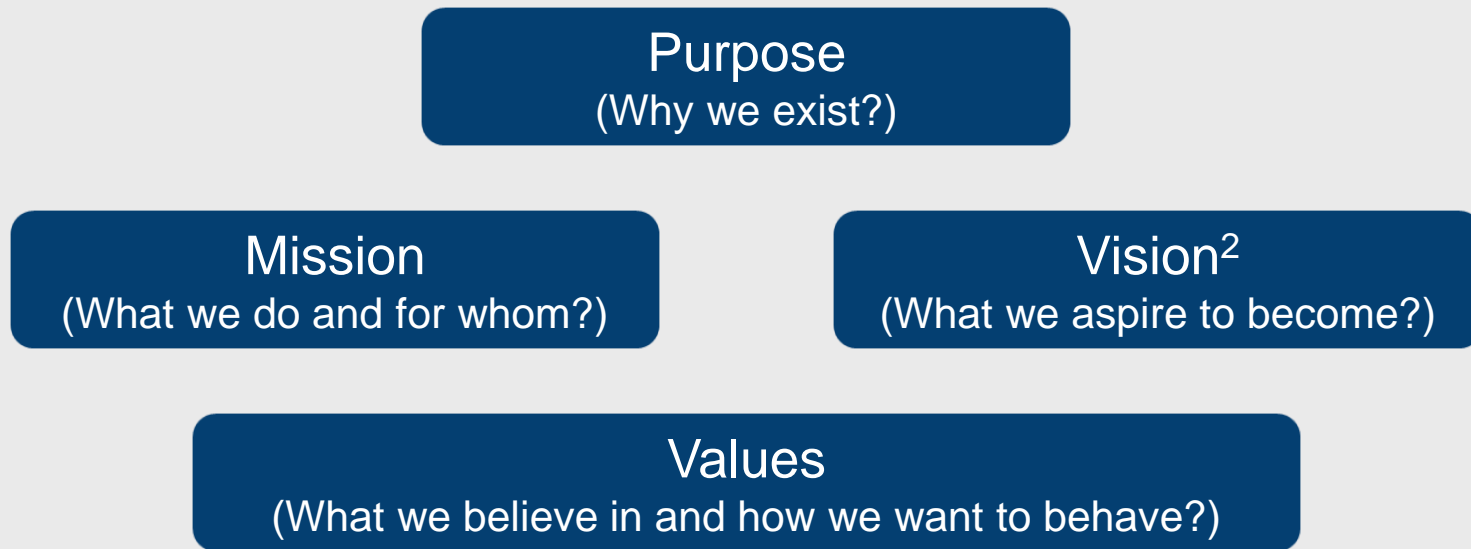
The Smart Manager should be able to participate to the elaboration of purpose, mission, values, vision statements; and ensure they are understood and applied

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**Tip #1 – Participate to setting Purpose – Mission – Values – Vision**

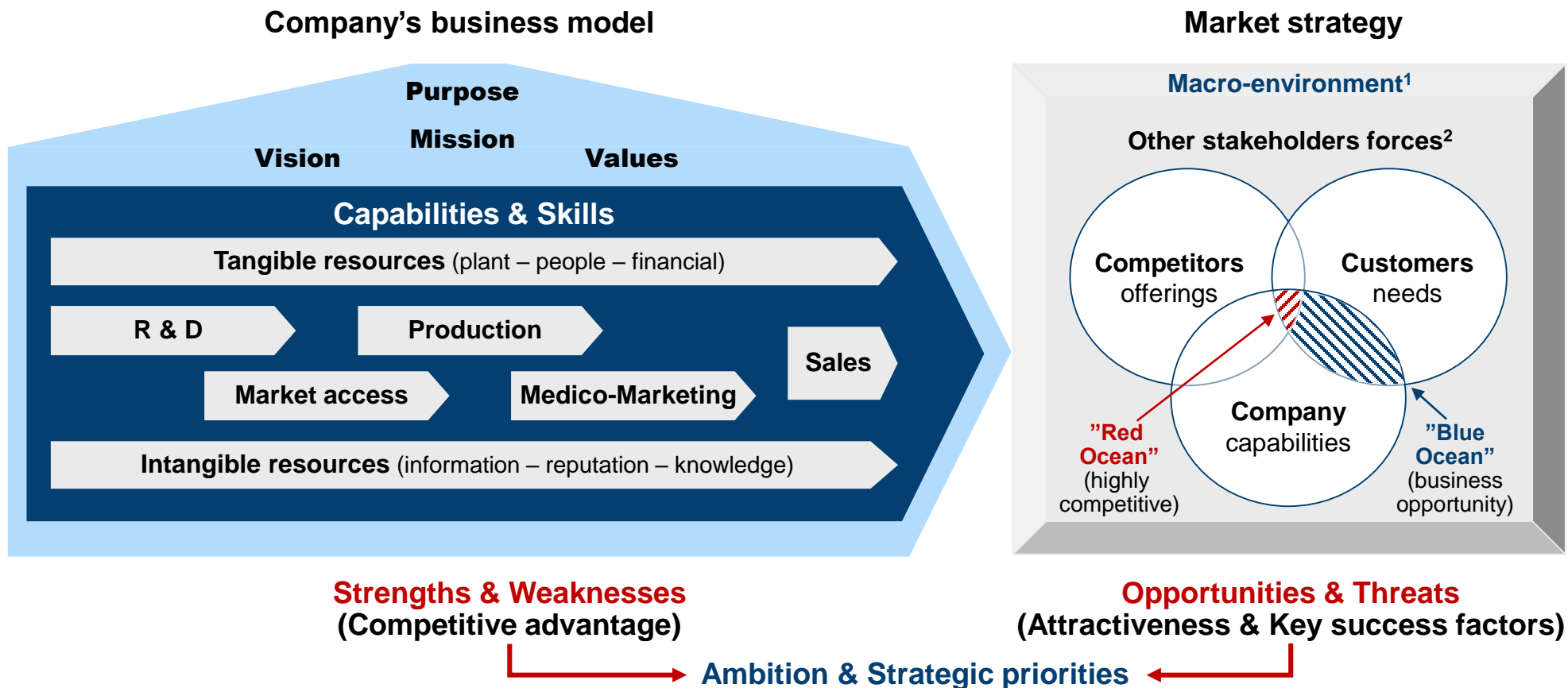
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- The Smart Manager **contributes** to develop the company: Purpose – Mission – Vision – Values
- He **translates** them at the level of its scope of responsibility<sup>1</sup>...
- He makes sure his **collaborators understand, share and comply with** them in their **daily activities**



The Smart Manager participates to the crafting of the market strategy and ensures the resources of the company he works for, are efficiently mobilized

**Tip #2 – Contribute to the strategy crafting**



Sources: Adapted after C. Kim et R. Mauborgne 2005 – D.J. Collis, HBR April 2008, M. Porter 1985 – Smart Pharma Consulting

<sup>1</sup> Political, legal, economic, socio-demographic and technological factors –  
<sup>2</sup> Including suppliers, new entrants, substitutes, complements



The Smart Manager will manage by mutual benefits (MBMB) to give a sense of purpose to his collaborators and thus to get their full and sustainable engagement

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**Tip #3 – Manage By Mutual Benefits**

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**MBO<sup>1</sup>**  
**(Management By Objectives)**

- Definition of **objectives agreed** by both management and employees
- Well-**adapted** to **vertical management** models
- However, by focusing on results, the way to achieve them (the planning) can be overlooked and lead to **suboptimal efficiency**
- Does not favor innovation nor flexibility

**MBMB**  
**(Management By Mutual Benefits)**

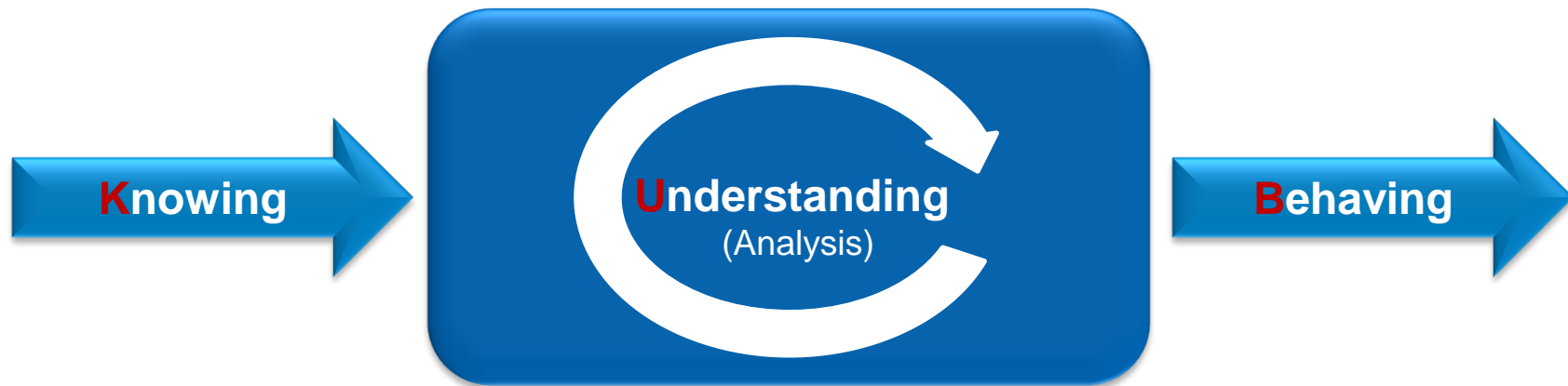
- Creates **mutual benefits** and **value** by **fulfilling** the respective **expectations** of employees and employers
- Maximize the probability to obtain the **full engagement** of employees
- Requires from managers to (better) satisfy collaborators ...
- ... to create **favorable conditions** to secure a **higher quality** of execution that will lead to **better results**

The Smart Manager should use the Smart Index to develop his own competence as well as the ones of his collaborators in a structured and efficient manner

**Tip #4 – Use the Smart Index (1/2)**

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

**S**mart index = **K**nowing x **U**nderstanding x **B**ehaving



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

The Smart Manager differs from the Good Manager, mainly by his much higher analytical and behavioral skills

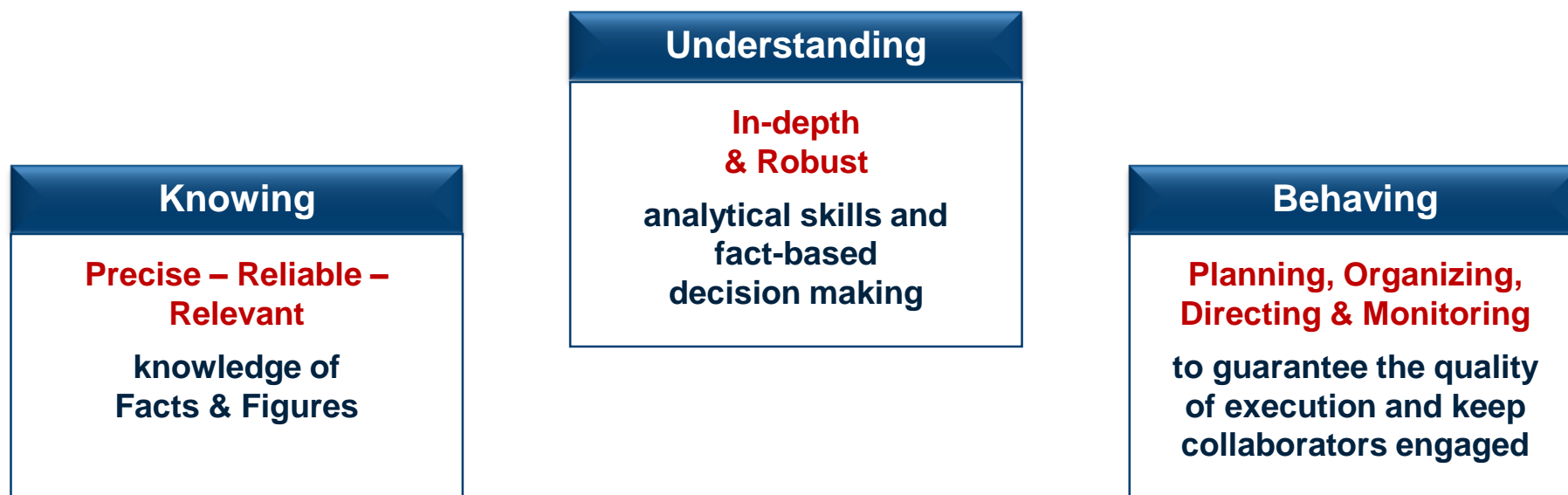
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**Tip #4 – Use the Smart Index (2/2)**

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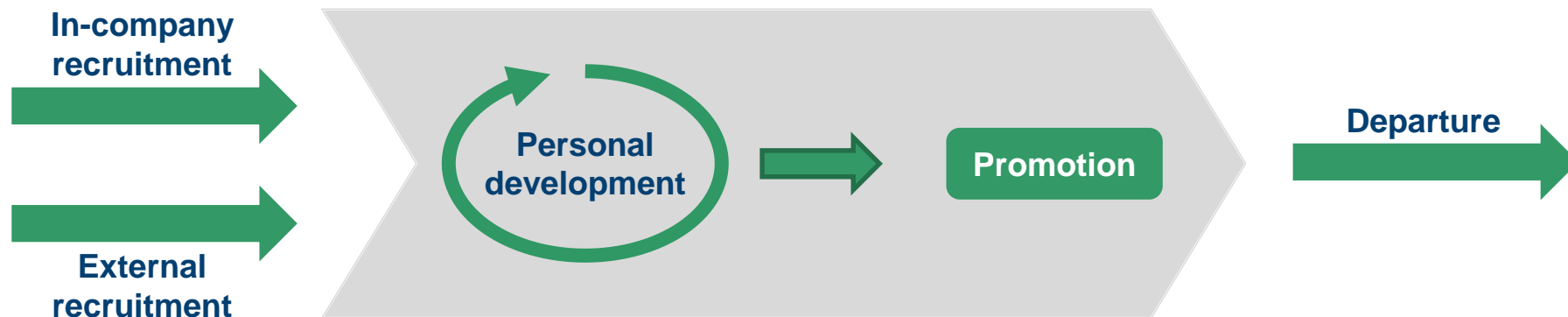
- Managers should focus their efforts on one or several components of the **Smart Index**:

**S**mart index = **K**nowing x **U**nderstanding x **B**ehaving



The Smart Manager is able to attract the best performers, to develop them and make them feel strongly engaged, while granting them the level of autonomy they deserve

**Tip #5 – Manage dynamically collaborators**



- Scout and 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*

**A Smart Manager creates the conditions to stimulate the passion of his collaborators for their job, which will prompt them to give their best to achieve their objectives**

**Tip #6 – Stimulate job passion**

Job passion is influenced by **six key drivers**:



Passion is expressed by:



*"Pleasure in the job puts perfection in the work"*

*Aristotle*

The Smart Manager will adopt a management model taking into account the business constraints, the company's goal, the strategic priorities and the collaborators' skills

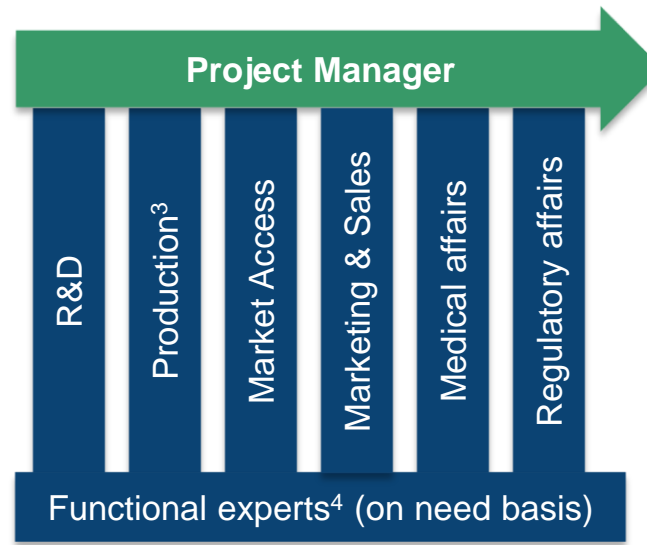
**Tip #7 – Adopt the right management model - Typology**

Vertical Management Model<sup>1</sup>  
(Hierarchical management)



Effective but too rigid to adapt to situational changes

Horizontal Management Model<sup>1</sup>  
(Transversal management)



Adapted to multifunctional tasks but problems of prioritization

Concentric Management Model<sup>2</sup>  
(Decentralized management)



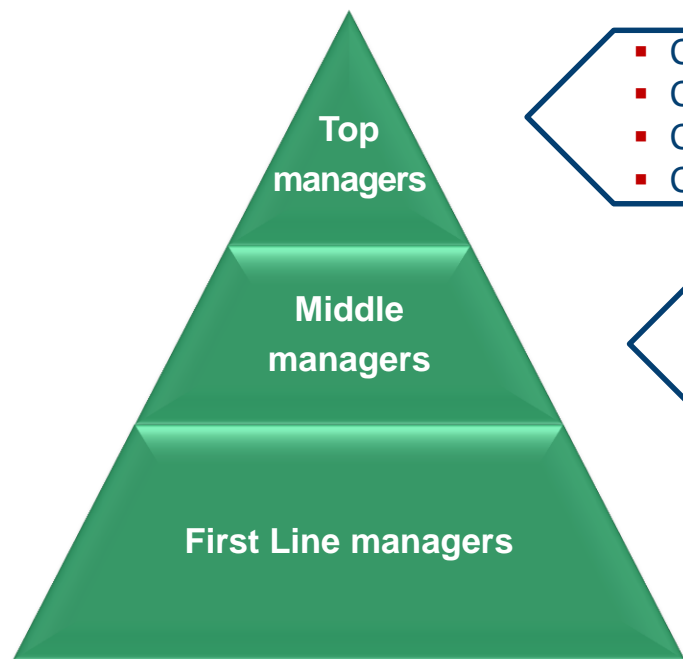
Adapted to fast-moving situations but requires a change in mindset

This “Command & Control” management model is efficient, facilitating decision-making and monitoring, but often too rigid to efficiently adapt to situational changes

**Tip #7 – Adopt the right management model - Vertical Management Model**

The vertical management model is hierarchical, with managers passing information and orders from the top to the bottom. The chain of command is well-defined and the level of control is in general high

**Roles & Responsibilities of Managers**



- Corporate purpose, mission, vision and values determination
- Corporate objectives, strategy (incl. M&A) and budget setting
- Corporate organization design and policy making
- Coordination and control of activities across departments<sup>1</sup>

- Implementation of the corporate strategy and organizational directives
- Crafting of the strategy and corresponding tactics to achieve the objective set for their department, while ensuring an efficient resource allocation
- Management of First Line Managers of their department
- Coordination and control of activities of their department

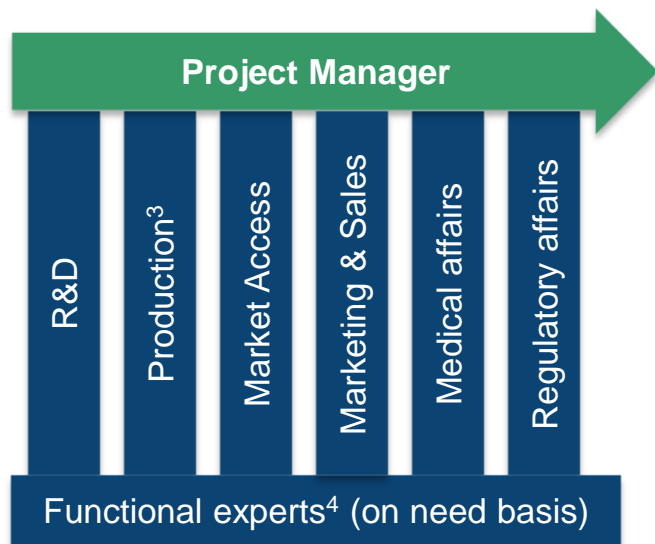
- Implementation of the strategy and the supportive operational activities, directly or, by managing their subordinates (e.g. medical representatives) within the limits of their budget
- Management, on a daily basis, of their subordinates

**Project managers role is to specify, organize and plan the execution of projects, while creating and sustaining the engagement of team members until their closing**

**Tip #7 – Adopt the right management model - Horizontal Management Model<sup>1</sup>**

The horizontal management model has a less-defined chain of command and the priority is given to work in teams around projects or specific tasks, led by project managers or team leaders, respectively

**Roles & Responsibilities of Project Managers**



- Project management requires the mobilization of financial and expert resources from different departments<sup>2</sup> on an *ad hoc* basis to achieve a clearly defined objective
- Project Managers, like managers of the Vertical Management Model, must plan, organize, direct and monitor the work of functional experts that have been assigned to the project and take corrective actions, whenever required
- Thus, they animate the project team (definition of roles and responsibilities, consciousness raising, mobilization, communication, delegation, control) to carry out the project to its term within the time and budget constraints set
- Functional experts report, during the course of the project, to the Project Manager whose authority flows horizontally across departments boundaries, but they also continue to report to the head of their department whose authority flows downwards (vertically)



**Concentric management model, like holacracy, is an hybrid model ensuring reliability of hierarchical organizations and adaptability of self-managed organizations**

**Tip #7 – Adopt the right management model - Concentric Management Model**

This is a decentralized model of management which organizes companies around the work that needs to be done instead of people who do it. It makes companies more flexible, more adaptable and more responsive to change

**Roles & Responsibilities**

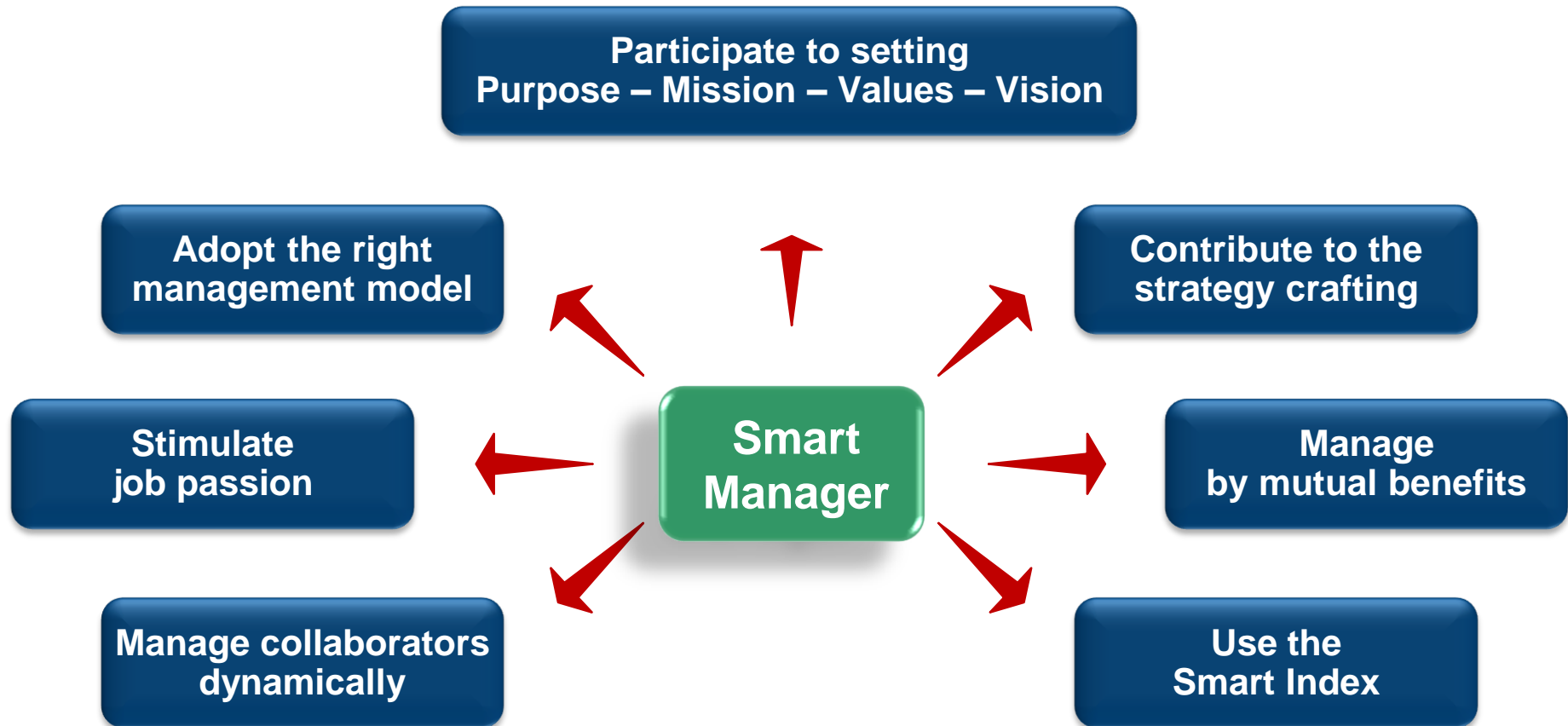
**Holacracy<sup>1</sup>**



- A “constitution” sets the rules of the game and redistributes responsibilities
- Holacracy is organized as a series of nested teams (circles) made up of a set of roles, grouped together around specific project teams, departments, business units, support functions, etc.
- Roles definition is constantly updated and clarified based on the day-to-day needs of the teams
- The people who know the most the work to be done are empowered
- People fill multiple roles, and thus are members of several teams
- Teams have their own governance which is an ongoing process
- Issues are added to the agenda when any team member senses a gap between how things are and how they could be addressed in a consensus manner
- Holacracy creates fast and agile organizations to solve tactical issues

Becoming a Smart Manager requires a permanent effort that should be focused, in priority, at excelling in each of the seven tips that have been proposed

**Seven tips to become a Smart Manager**



Smart Pharma Consulting can help pharma companies transform Good Managers into Smart Managers through various modes of collaboration

**How can Smart Pharma Consulting help Managers become Smarter?**





**The Smart Manager Series (#1)**

***Time Management***

**Save 3 hours  
per day  
&  
Boost your  
efficiency**

**8  
Practical  
Recommendations**

August 2017

  
**Smart Pharma Consulting**

*"Time being priceless, don't waste it!"*



## Introduction

**Time is a limited resource which must be used efficiently to achieve the objectives set**

### Time at work

- Employees of companies receive a salary in exchange for their competence...
- ... which will be expressed during a finite period of time<sup>1</sup>
- The issue for employers and employees is to make the best use of this limited resource
- Thus, the key question to be answered is:

**“How to boost employees productivity by properly allocating time to meet their objectives?”**

### Time management at work

- We all run after time
  - To help you make a better use of your time, Smart Pharma Consulting proposes easy-to-implement method and tools
  - If properly executed, you and your teams can expect to:
    - Save more than three hours per day
    - Boost significantly efficiency and efficacy
- while improving quality of life

***“Time management doesn’t give more time, just helps make a better use of it”***



## Express Self-diagnosis

**If one of these six statements reflects your situation, then read this document**

How well do you manage your time?





## Method to Optimize your Time

**To better manage your working time, implement the following method**

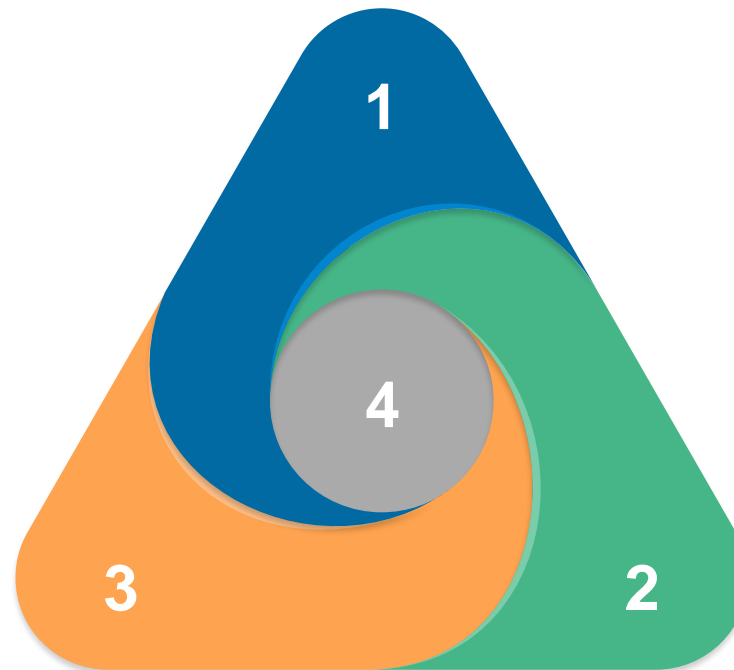
A four-step easy-to-implement method

### **4. Tracking & sharing outcomes**

Systematically track the impact of the applied solutions and convince your colleagues to adopt the same method

### **3. Planning & implementation**

The solutions selected to improve time management will be carefully planned and rigorously applied



### **1. Situation analysis**

During the first step, you will identify the main time wasters

### **2. Management of time wasters**

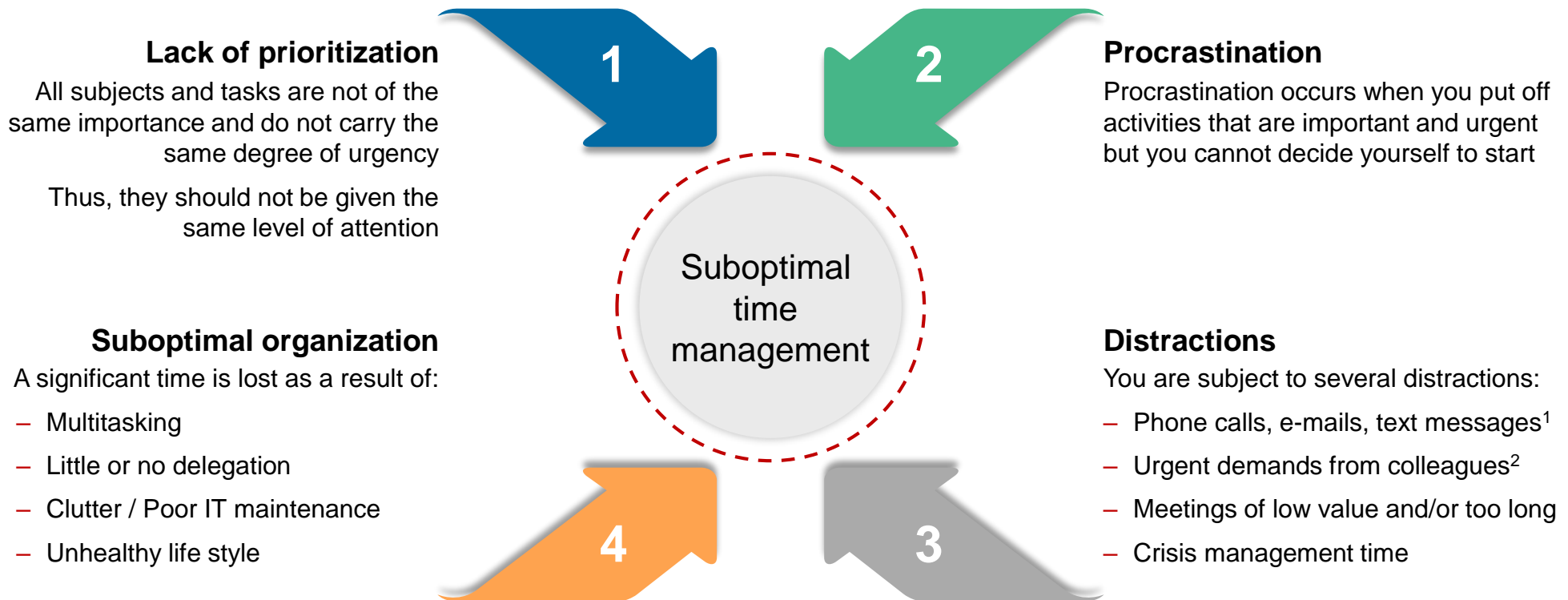
The second step will consist in defining solutions to eliminate the time wasters or, at least, limit their noxious effect



## 1. Situation Analysis

**You must carefully identify the main time wasters**

Main factors responsible for poor time management



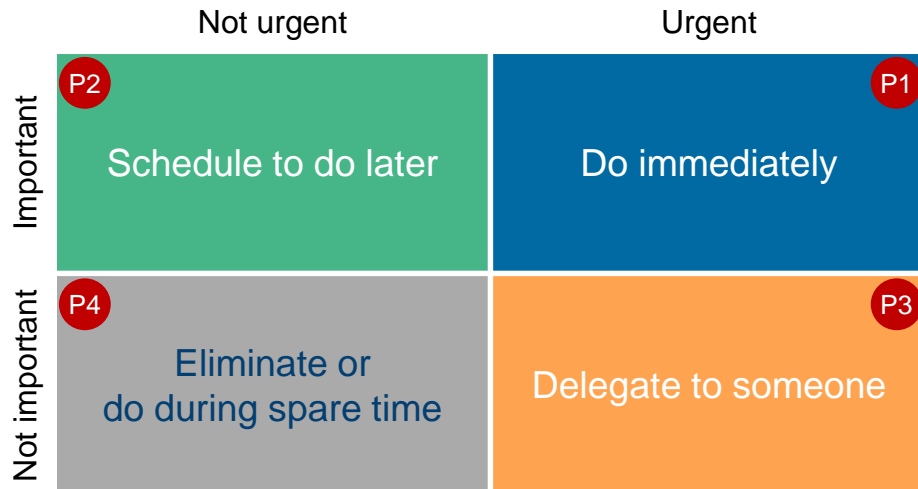




## 2. Management of Time Wasters

The Eisenhower Matrix helps selecting activities to focus on and those to eliminate

### 1. Prioritization of activities: Eisenhower<sup>1</sup> Matrix



Make a specific to-do list (e.g. for the day, the week, the month) with all the things to get done

- The Eisenhower Matrix is a tool to **prioritize** activities based on importance and urgency
- Important activities contribute to meet long-term personal and/or corporate goals and urgent ones require immediate attention
- A great attention should be paid at evaluating:
  - What activities should be done?
  - When and by whom?
- This matrix helps sorting out activities to focus on and those that should be ignored
- Then a daily, weekly, monthly... **schedule** of activities will be set considering their degree of priority **based on importance and urgency**

**P1** Priority ranking



## 2. Management of Time Wasters

**By putting off priority tasks, you will miss deadlines and impair quality of outcomes**

### 2. Avoidance of procrastination



***“Never leave that till tomorrow which you can do today” – Benjamin Franklin***



## 2. Management of Time Wasters

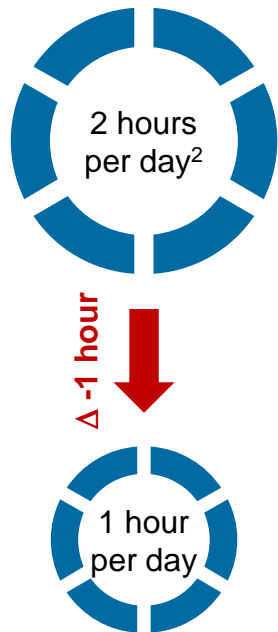
**Better management of NICTs<sup>1</sup> and meetings should free 3 hours per day**

### 3. Reduction of key distractions

Phone calls, e-mails, text messages, instant messaging chats, Twitter, Facebook, LinkedIn, etc.



Meetings of low value or too long

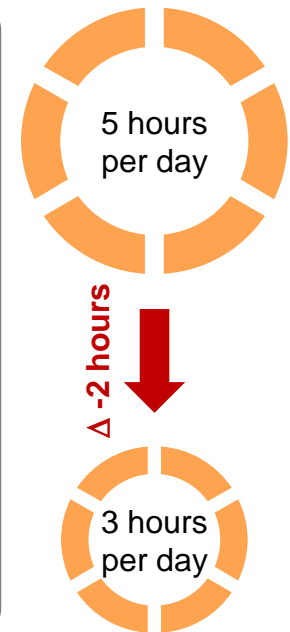


**Save one hour** per day by better managing electronic time wasters, as follows:

- **Unplug** (switch off phones, disconnect instant messaging, close the door<sup>3</sup>, etc.) especially **when you need to concentrate on priority tasks**
- **Check** e-mails, text messages, phone calls, etc., **3-4 times a day** and...
- ... **set aside 2 time slots** to **respond** to them, before lunch and leaving the office
- **Unsubscribe** from or **block email lists** if you don't want to receive their content<sup>4</sup>
- **Don't feel obliged to pick phone calls**<sup>4</sup>

**Save two hours** per day on meetings and make them more efficient by:

- **Reducing their time by 25%** (e.g. 45 minutes instead of one hour)
- **Cancelling informative meetings**, where no decisions are made (**1/5 on average**)
- **Preferring teleconferences** when participants are from different locations
- **Inviting only people** that are **absolutely required** and **who will benefit** from it
- **Preparing** (precise objective, agenda) and **managing** them **rigorously** (no off-topic discussions, time-keeping)





## 2. Management of Time Wasters

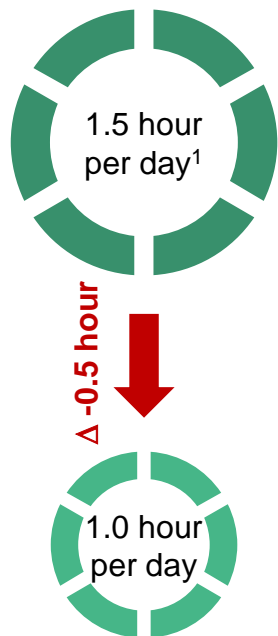
**A proper management of unplanned demands or events could save 1 hour per day**

## 3. Reduction of key distractions

Urgent demands from hierarchy, peers, subordinates, etc.

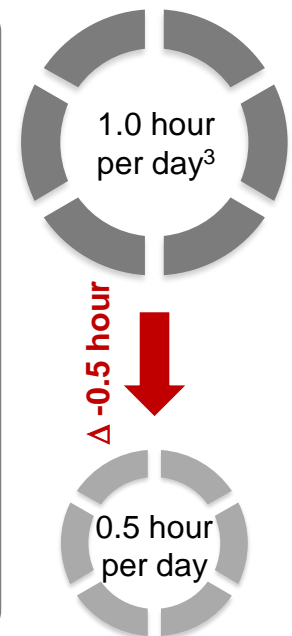


Crisis management time



- Don't take more than you can handle
- Avoid saying “maybe” or “I’ll see”, just say “Yes” or “No” when you are asked to carry a task
- You should dare to say “No” and explain tactfully why you can’t do it²
- Help the demander analyze the situation which can make him realize that:
  - His demand may not be so urgent and propose longer deadlines to do it
  - It could be done by another colleague who may have more availability and be even more competent or...
  - ... outsourced to an agency

- “Crisis management time” such as a last moment replacement of a colleague at a meeting or settlement of a dispute with health authorities will disrupt daily and/or weekly schedules
- To properly manage these urgencies, you need to put them in perspective with your scheduled priorities which will enable you to achieve your goals
- If you are familiar with basic time management rules, it will be easier to properly allocate your time...
- ... avoiding to over-invest in these urgent events, at the expense of your priorities





## 2. Management of Time Wasters

If multitasking is a false good idea, delegating is an imperative

### 4. Getting better organized<sup>1</sup>

Avoid multitasking



Delegate



- Studies have shown that **multitasking increases** the time required to accomplish different tasks when compared to doing them in a sequential manner
- Actually, switching one task to another **impairs**:
  - **Productivity**
  - **Quality** of the work done
- You should **work in sequence**, one task at a time, to save time and deliver higher quality outcomes
- **Close off** the applications you are not using...
- ... the **tabs in your browser** that may distract your attention from the task you are doing

- **Delegate**, whenever possible, tasks that are essential but which **can be done by someone else**; and sometimes better because she/he is **more competent** or has **less time pressure**
- Don't underestimate the importance to:
  - Explain the **objective** of the task
  - Precise **what you expect**
  - Indicate the **deadlines**
  - **Motivate** the person who is going to do the task
  - Not **micromanage**
- **Outsourcing** to an agency or **purchasing goods/services** that will save your time are other options to be considered



## 2. Management of Time Wasters

Good organization and balanced life style contribute to improve work efficiency

### 4. Getting better organized<sup>1</sup>

Eliminate clutter / maintain your equipment



- Clear your desk of everything except the work you intend to do during the day
- Adopt an effective filing system for electronic and hard copies of your documents
- Keeping a good system for filing e-mails, computer documents and papers will save many hours in the long run
- Take the habit to save every 15 to 20 minutes your work on your computer, especially on PowerPoint and Excel
- Make sure your computer equipment is well maintained, that the antivirus and other data protection software are updated regularly



Keep a healthy balance between work and home life



- Healthy lifestyle will boost your energy and motivation, clear your mind and increase your productivity
- Thus, it is strongly recommended to:
  - Sleep enough (~seven hours, depending on individuals)
  - Have a healthy and balanced diet (light lunches to prevent postprandial sleepiness and remain alert)
  - Exercise 2-3 times a week (e.g. swimming, running) for ~2 hours to increase your stamina, better manage your stress
  - Maintain a good balance between work and private life
  - Take breaks (5-10 minutes in morning and afternoon) at work to breathe, relax, socialize at the coffee machine...



### 3. Planning & Implementation

**Take time to plan carefully your activities and you will end up saving time**

Prioritization of tasks: Activity planning tools

Illustrative

Weekly time log	Monday	Tuesday	Wednesday	Thursday	Friday
Morning					
Lunchtime					
Afternoon					
Evening					

Morning time log	Activities	Priority <sup>1</sup>	Afternoon Time log	Activities	Priority <sup>1</sup>	Remarks
≤8:30			14:00			
9:00			14:30			
9:30			15:00			
10:00			15:30			
10:30			16:00			
11:00			16:30			
11:30			17:00			
12:00			17:30			
12:30			18:00			
13:00			18:30			
13:30			≥19:00			

- The purpose of this tool is to help you organize your activity and make sure you will focus your time and effort at your 2-3 top priorities (P1) to reach your main goals and set deadlines
- It is not only a planning tool but also a diagnostic tool to check if you allocate your time in an optimal way
- Your most challenging<sup>2</sup> activities should be slotted into your most productive (high-energy) time of the day
- The time log should be filled up (on a notebook or an electronic device<sup>3</sup>), ideally, at the end of the previous week or day, accordingly, which should not take more than 10-15 minutes



## 4. Tracking & sharing outcomes

**Time management is an ongoing process which should involve all employees**

### Tracking outcomes

- **Tracking** your planned **activities** will enable you to:
  - Analyze **whether** the **time** allocated **reflects** your **priorities**
  - Calculate the potential **gaps** between **planned** and **effective time** spent per activity and **find the reasons**
- Based on these information, you can:
  - **Rectify** your time management **mistakes**
  - **Look for solutions** to better use your time
  - **Measure** your **improvements** from one period to another
- **Tracking** can be done **with** the help of **time logs** such the activity planning tools we have proposed<sup>1</sup>, Gantt charts commonly used for project management, specific time tracking software or time-saving apps

### Sharing outcomes

- Once you **get tangible** results through the application of Time Management recommendations, you can try to **engage** your close **colleagues**, either superiors, subordinated or pairs, to follow them
- **Sharing** your “*positive*” **outcomes** will **benefit**:
  - **Your colleagues** who should obtain a similar added-value if they apply the same recommendations
  - **You** because your colleagues will be more sensitive to distractions they may generate and pay more attention to avoid or limit them
  - **The overall organization** through an overall increase of its collaborators productivity and quality of works





## Our 8 Practical Recommendations...



**... to help you save more than 3 hours per day & boost your efficiency**

- 1** Avoid meetings before 10:30 am to focus on your key activities requiring the greatest concentration<sup>1</sup>
- 2** Do not attend meetings if you are not essential or if it doesn't contribute to meet your goals<sup>2</sup>
- 3** Shorten the usual one-hour meetings to 45 minutes and suggest your colleagues to do the same
- 4** Batch similar tasks together (e.g. e-mails reply, administrative work, etc.)
- 5** Avoid meetings after 5:30 - 6:00 pm to keep time available to answer your phone calls, e-mails, etc.,
- 6** Keep a one-hour buffer time per day for absorbing unexpected extra work or in case you fall behind on your scheduled activities of the day
- 7** Keep 10 minutes, at the end of the day, to organize your next working day
- 8** Impose yourself strict rules to minimize the time spent dealing with unsolicited or irrelevant messages

***“By saving 3 hours per day, you will get the equivalent of 1.5 more day per week”***



## How can Smart Pharma Consulting help you?

We propose intra-company services to better manage time

### Three Time Management services

#### Training seminars<sup>1</sup>

- We organize one- to two-day intra-company seminars for groups
- We share methods, simple tools, tips and tricks to optimize time management of individuals or teams
- We propose practical exercises in the form of role plays, case studies, simulations, etc.

#### Transformational projects

- We help companies set customized rules and develop specific means to optimize the time management at global, affiliate, department or functional level
- We produce guidelines and support tools regarding the management of projects, meetings and distractions; internal and external communication (incl. writing of e-mails and text messages, phone calls, etc.)

#### Individual coachings<sup>1</sup>

- We provide individual support for a period of three to six months
- We co-develop a specific approach, agree on the rules and enabling tools to improve time management
- We carry out a bi-monthly review to analyze the progress of the situation
- We set a hotline for the coachee



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## This position paper proposes strategic and operational methods, tools and advice to boost Medical Science Liaisons (MSLs) competence and performance

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### Context & Objective

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- Medical Science Liaisons (MSLs) play a pivotal role to maintain a close relationship with KOLs<sup>1</sup> who are instrumental in:
  - Developing new products through their collaboration in pre-clinical and / or clinical trials
  - Raising the awareness and the preference – indirectly or directly – for their products in the mind of HCPs<sup>2</sup> but also of health authorities, PAGs<sup>3</sup>, individual patients, etc.
- **The increasing role of Medical Science Liaisons (MSLs) results from:**
  - New molecular entities becoming more and more complex...
  - ... and mainly prescribed by specialists, less and less inclined to be informed by medical reps
- **In this position paper, Smart Pharma Consulting proposes:**
  - **Methods, tools and advice to boost MSLs competence and performance**
  - **KOL Partnership Model to recruit and manage KOLs in a more efficient and effective way**

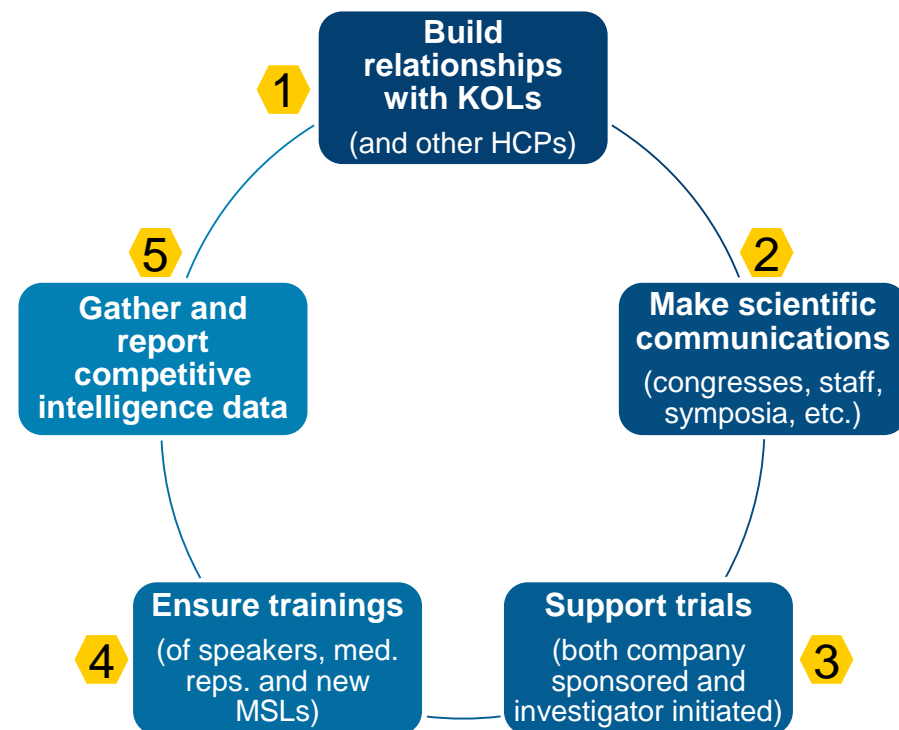
**MSLs are the field team of medical affairs in pharma companies, who are dedicated to the development of relationships with KOLs and to high-level scientific communications**

## Overview

### MSLs: Medical Science Liaisons<sup>1</sup>

- MSLs are one of pharma companies' field teams dedicated to enhance the full exchange of **scientific information** with physicians, especially with KOLs
- MSLs have a more robust scientific background than medical representatives, such as: **MSc, MD, Pharm. D, PhD degrees** (90% of them have a doctorate degree)
- MSLs were first established by **Upjohn Pharmaceuticals** (now Pfizer) in **1967** with the objective **to build a strong relationship with KOLs**
- The central activity of MSLs is to develop long-term, peer-to-peer **relationships with KOLs**
- MSLs are in most cases affiliated to the **medical affairs department** (whereas med reps. are affiliated to the sales / marketing department)

### Core activities<sup>2</sup> of MSLs

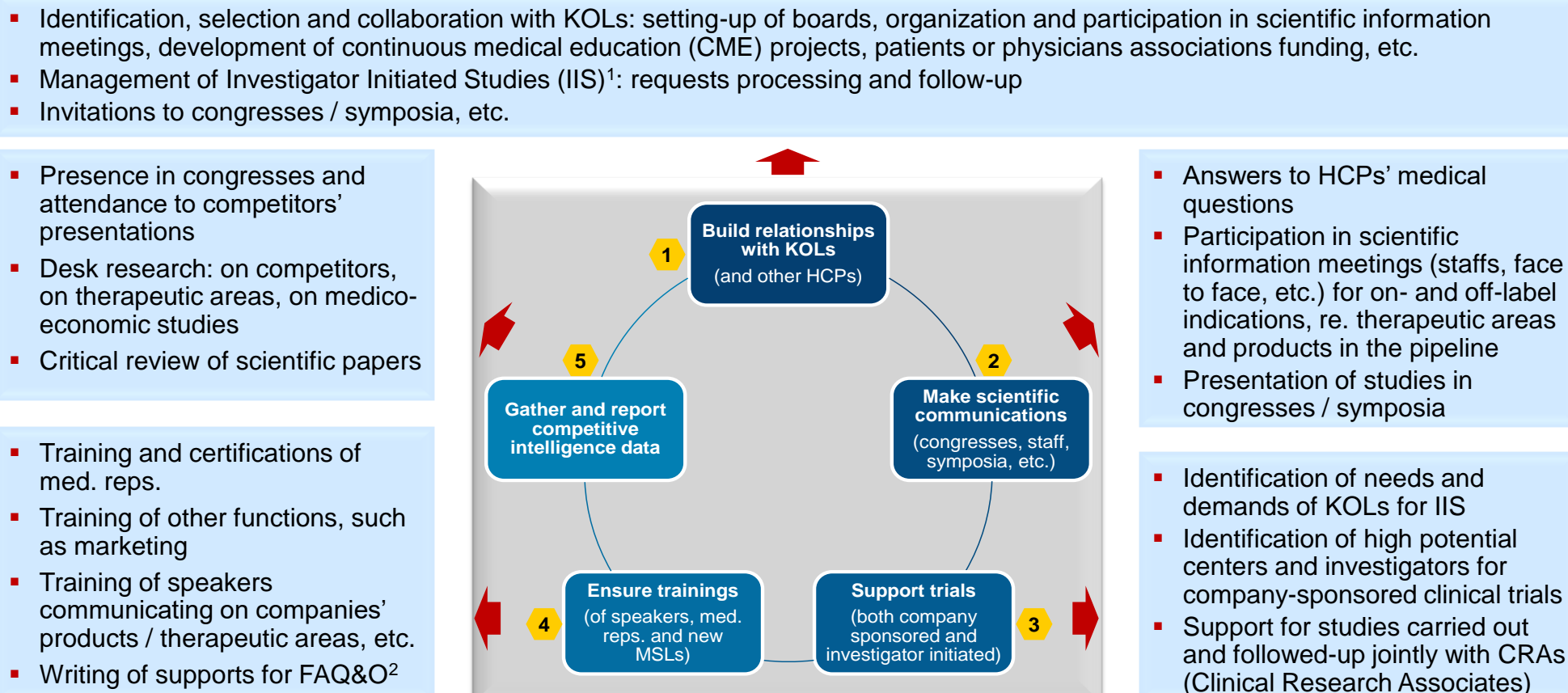


Sources: MSL Society – “An insight into the emerging role of regional medical advisor in the pharmaceutical industry”, Perspectives in Clinical Research, 2013 – Smart Pharma Consulting analysis

<sup>1</sup> Other names than MSLs can be used by pharmaceutical companies such as: Medical Liaisons, Regional Medical Managers, Regional Scientific Managers, Scientific Affairs Managers, Medical Information Scientists, Clinical Liaisons – <sup>2</sup> Excluding administrative time

## MSLs are often asked to cover a large scope of activities in collaboration with both internal and external stakeholders

### MSLs' detailed core activities

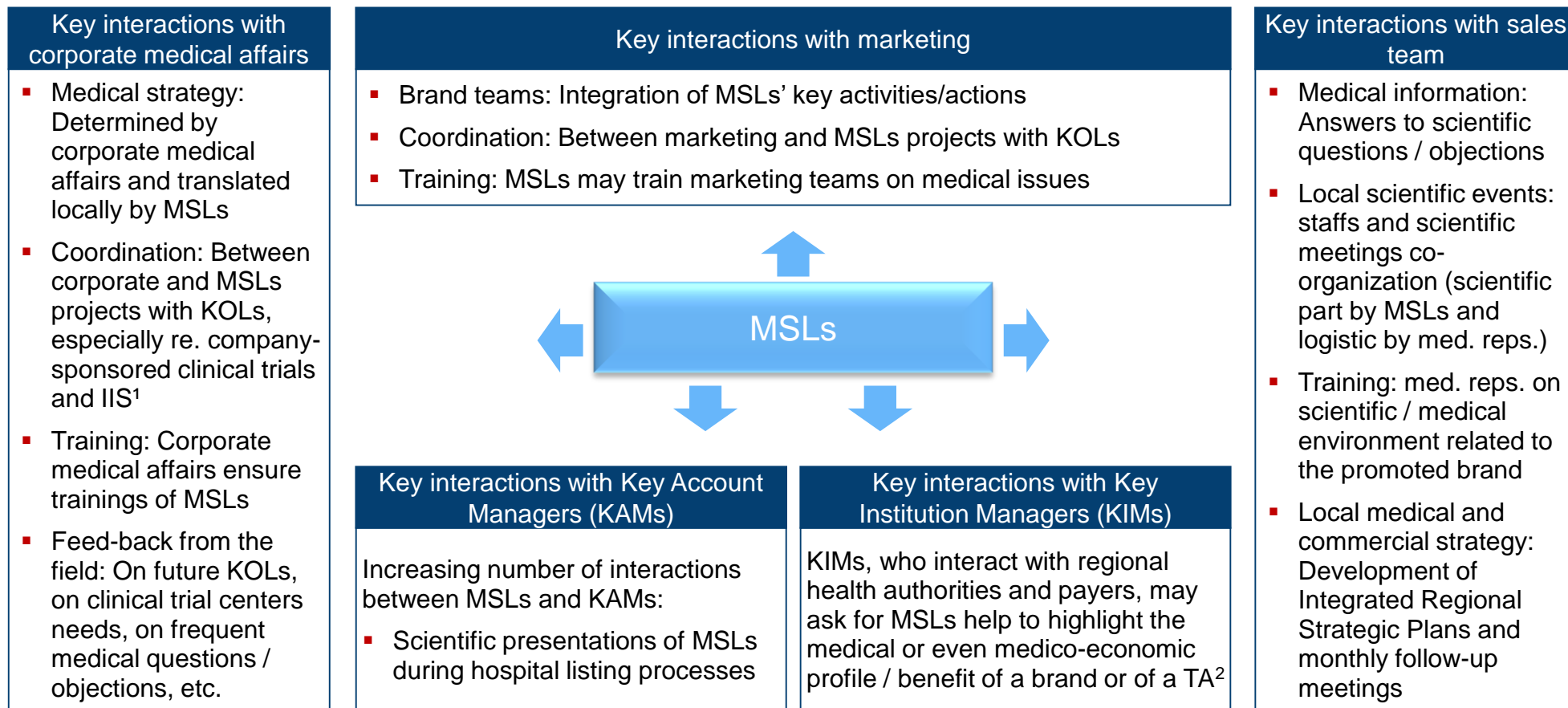


Sources: "An insight into the emerging role of regional medical advisor in the pharmaceutical industry", Perspectives in Clinical Research, 2013 – Interviews with 5 MSLs – Smart Pharma Consulting analysis

<sup>1</sup> Also called: Investigator-Initiated Trials or IIT – <sup>2</sup> Frequently Asked Questions & Objections

**MSLs must support KIMs<sup>1</sup> who facilitate regional market access, KAMs<sup>2</sup> who ensure listing of products at hospital level and marketing and sales reps who promote them**

#### The transversal role of MSLs



Sources: "The changing role of the modern MSL", Pharmaceutical Market Europe, October 2015 – Interviews with 5 MSLs – Smart Pharma Consulting analysis

<sup>1</sup> Key Institution Managers – <sup>2</sup> Key Account Managers – <sup>3</sup> Investigator Initiated Studies – <sup>4</sup> Therapeutic Area

## MSLs teams face recurrent issues that can be addressed if pharma companies implement the relevant actions

### Six main issues facing MSLs teams

	Key issue	What to do?
1	<b>Distinction from sales / marketing</b>	<ul style="list-style-type: none"> <li>Information campaigns to be carried out to inform stakeholders of the specific role of MSLs</li> <li>Information should be provided through calls</li> </ul>
2	<b>Disconnection with corporate initiatives</b>	<ul style="list-style-type: none"> <li>The coordination should be improved by implementing standard communication processes and rules</li> </ul>
3	<b>Distraction from core activities</b>	<ul style="list-style-type: none"> <li>MSLs' responsibilities and objectives should be clearly defined and internally communicated through information campaigns</li> </ul>
4	<b>Extensive geographical zones</b>	<ul style="list-style-type: none"> <li>Alternative communication technologies such as web conferencing, e-mailing, teleconferences, etc., should be considered</li> </ul>
5	<b>Complex regulatory environment</b>	<ul style="list-style-type: none"> <li>Pharma companies should focus on MSLs' compliance with local regulations...</li> <li>... which should be carefully monitored</li> </ul>
6	<b>Trend towards specialization</b>	<ul style="list-style-type: none"> <li>Pharma companies should keep on investing on their MSLs' scientific training</li> </ul>

Sources: "Implementing a MSL team", Publicis Touchpoint – "Aligning the Activities and Goals of Medical Science Liaison Teams for Strengthened Corporate Sustainability", MSL World – Interviews with 5 MSLs – Smart Pharma Consulting analysis



**MSLs' most important challenge is certainly to create highly valued interactions and trusted collaborative relationships with KOLs to support companies and products**

#### MSLs' challenges – Required skills – Expected outputs

MSLs' challenges	<ul style="list-style-type: none"> <li>Keeping up with the latest scientific information</li> <li>Building strong and sustainable relationships with KOLs</li> <li>Managing multiple and diversified tasks</li> <li>Complying with national regulations and internal code of conducts</li> <li>Ensuring effective coordination with collaborators</li> </ul>	
Required skills	Expected outputs	
<ul style="list-style-type: none"> <li>Excellent scientific knowledge and understanding to carry out peer-to-peer discussions during interactions with KOLs</li> </ul>	<ul style="list-style-type: none"> <li>Ability to inform, challenge and / or convince KOLs based on robust and updated scientific evidence</li> </ul>	
<ul style="list-style-type: none"> <li>Strong communication skills to properly position:               <ul style="list-style-type: none"> <li>– The company's therapeutic expertise</li> <li>– A given product at pre- or post-launch stage</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Convince KOLs to carry out research or clinical studies</li> <li>Convince KOLs to support the company's products</li> </ul>	
<ul style="list-style-type: none"> <li>Ability to manage projects with KOLs (e.g. while supporting investigators-initiated studies or company-sponsored clinical trials)</li> </ul>	<ul style="list-style-type: none"> <li>Identification of clinical research opportunities with KOLs</li> <li>Effective implementation of clinical research trials</li> </ul>	
<ul style="list-style-type: none"> <li>Ability to train / teach and / or develop support documents for companies' collaborators and / or HCPs</li> </ul>	<ul style="list-style-type: none"> <li>Improvement of participants' knowledge, understanding of the disease area and of the benefits of the company's products</li> </ul>	
<ul style="list-style-type: none"> <li>Capture and share insight gathered through interactions between KOLs' and all customer-facing teams</li> </ul>	<ul style="list-style-type: none"> <li>Profiling and selecting the relevant KOLs to partner with</li> <li>Fulfilling of KOLs needs related to MSL activities</li> </ul>	
<ul style="list-style-type: none"> <li>Cooperate and coordinate activities with other customer-facing collaborators and corporate teams interacting with KOLs</li> </ul>	<ul style="list-style-type: none"> <li>MSLs being the preferential contact of KOLs, they will ensure consistent interactions and address potential issues</li> </ul>	
<ul style="list-style-type: none"> <li>Comply with national regulations and ethical considerations regarding disseminated information (e.g. off-label)</li> </ul>	<ul style="list-style-type: none"> <li>Prevent the company to be sued and to be fined</li> </ul>	
<ul style="list-style-type: none"> <li>Ability to manage time, set priorities and adjust unforeseen changes inherent to MSLs' job</li> </ul>	<ul style="list-style-type: none"> <li>Timely and proper execution of multiple tasks under the responsibility of MSLs</li> </ul>	

Sources: "The changing role of the modern MSL" Pharmaceutical Market Europe October 2015 – Smart Pharma Consulting analysis

# MSLs' activities should be integrated in a Regional Strategic Plan to ensure synergies with marketing, sales, market access and patient adherence departments' activities<sup>1</sup>

## Integrated Regional Strategic Plan – Principle



**MSLs' activities should be defined in an Integrated Regional Strategic Plan in coordination with marketing, sales, market access and adherence departments**

### **Integrated Regional Strategic Plan – Structure of the Medical Section**



#### **Structure**

- Situation analysis
  - KOLs mapping (level of influence – advocacy behavior)
  - Activity review (quantitative and qualitative analysis):
    - KOLs' partnership (calls, preparation of staff meetings, invitation to congresses, support of IIS<sup>1</sup> and / or of the company-sponsored clinical trials, etc.)
    - Participation in congresses
    - Training of speakers, of marketing and sales collaborators
    - Support to Key Institution Managers (KIMs) in charge of regional market access and patient adherence programs
    - Support to Key Account Managers (KAMs) in charge of product listing at hospital (or purchasing platform) levels in highlighting medical benefits
    - Competitive intelligence data gathering and analysis
  - Measurement and assessment of activities' impact
  - MSL Advanced SWOT analysis<sup>2</sup>
- Ambition & strategic priorities
  - Ambition setting
  - Strategic priorities to fulfill the ambition set (MSL Strategy Card)<sup>2</sup>
  - Key activities to support strategic priorities:
    - Shared activities with other departments (e.g. marketing, sales, KAMs, KIMs)
    - Non-shared activities
  - Monitoring of the quality of execution and impact of activities

The Advanced SWOT is a useful tool to help MSLs analyze and evaluate regional medical opportunities and threats as well as their own competitive position

Integrated Regional Strategic Plan – Specific tools of the Medical Section (1/3)

**MSL Advanced SWOT**

Opportunities	Relative importance <sup>1</sup>	Threats	Relative importance <sup>1</sup>
<p><b>What regional changes are likely to favor the medical environment?</b></p> <p><i>National &amp; regional regulations</i> relating to MSLs' activities (e.g. off-label communication, invitation process to congresses, grants, etc.)</p> <p><i>KOLs' opinion &amp; position</i> re. the company and its products, KOL's level of influence</p> <p><i>Scientific events</i>: regional congresses, other meetings</p>		<p><b>What regional changes are likely to disfavor the medical environment?</b></p> <p><i>National &amp; regional regulations</i> relating to MSLs' activities (e.g. off-label communication, invitation process to congresses, grants, etc.)</p> <p><i>KOLs' opinion &amp; position</i> re. the company and its products, KOL's level of influence</p> <p><i>Scientific events</i>: regional congresses, other meetings</p>	
Strengths	Relative importance <sup>1</sup>	Weaknesses	Relative importance <sup>1</sup>
<p><b>What are the absolute or relative advantages of the company's medical activity at regional level vs. competition?</b></p> <p>1 <i>Relationships with KOLs</i>: quality and sustainability</p> <p>2 <i>Scientific communications</i>: congresses, staff meetings, symposia, etc.</p> <p>3 <i>Support to trials</i>: company-sponsored trials and IIS<sup>2</sup></p> <p>4 <i>Training</i> of speakers, med. reps, new MSLs, etc.</p> <p>5 <i>Competitive intelligence</i>: data gathering and analysis</p>		<p><b>What are the absolute or relative disadvantages of the company's medical activity at regional level vs competition?</b></p> <p>1 <i>Relationships with KOLs</i>: quality and sustainability</p> <p>2 <i>Scientific communications</i>: congresses, staff meetings, symposia, etc.</p> <p>3 <i>Support to trials</i>: company-sponsored trials and IIS<sup>2</sup></p> <p>4 <i>Training</i> of speakers, med. reps, new MSLs, etc.</p> <p>5 <i>Competitive intelligence</i>: data gathering and analysis</p>	

The MSL Strategy Card will help design a “one-page strategy” including his ambition, the strategic priorities to meet it and the corresponding medical activities

**Integrated Regional Strategic Plan – Specific tools of the Medical Section (2/3)**



Sources: Smart Pharma Consulting

<sup>1</sup> To support the corresponding strategic priority

Qualifying MSLs' activity is a challenge, however, several qualitative and quantitative metrics can be considered for pharma companies to ensure a proper monitoring

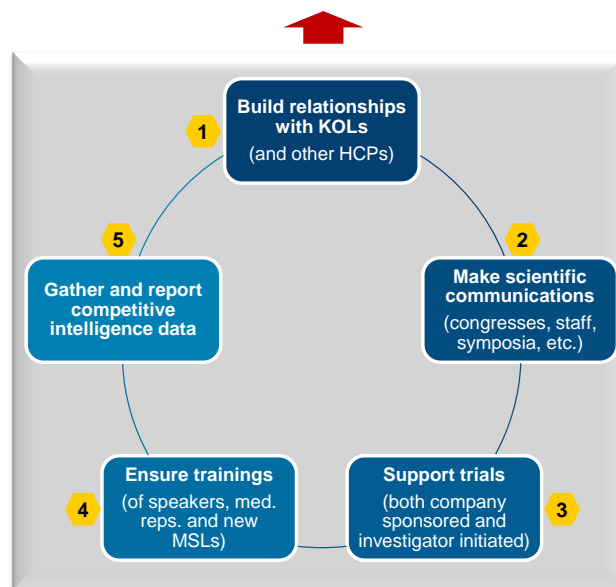
**Integrated Regional Strategic Plan – Specific tools of the Medical Section (3/3)**

**Recommendations of metrics to monitor MSLs' activities**

- Number of partnerships initiated with KOLs
- Number of contacts and / or time spent with KOLs in face-to-face meetings, teleconferences, staff meetings, etc.
- Qualitative assessment of KOLs partnership management

- Number of competitive reports
- Number of congresses reviews
- Quality of information gathered

- Number of people trained
- Qualitative feedbacks of trained people



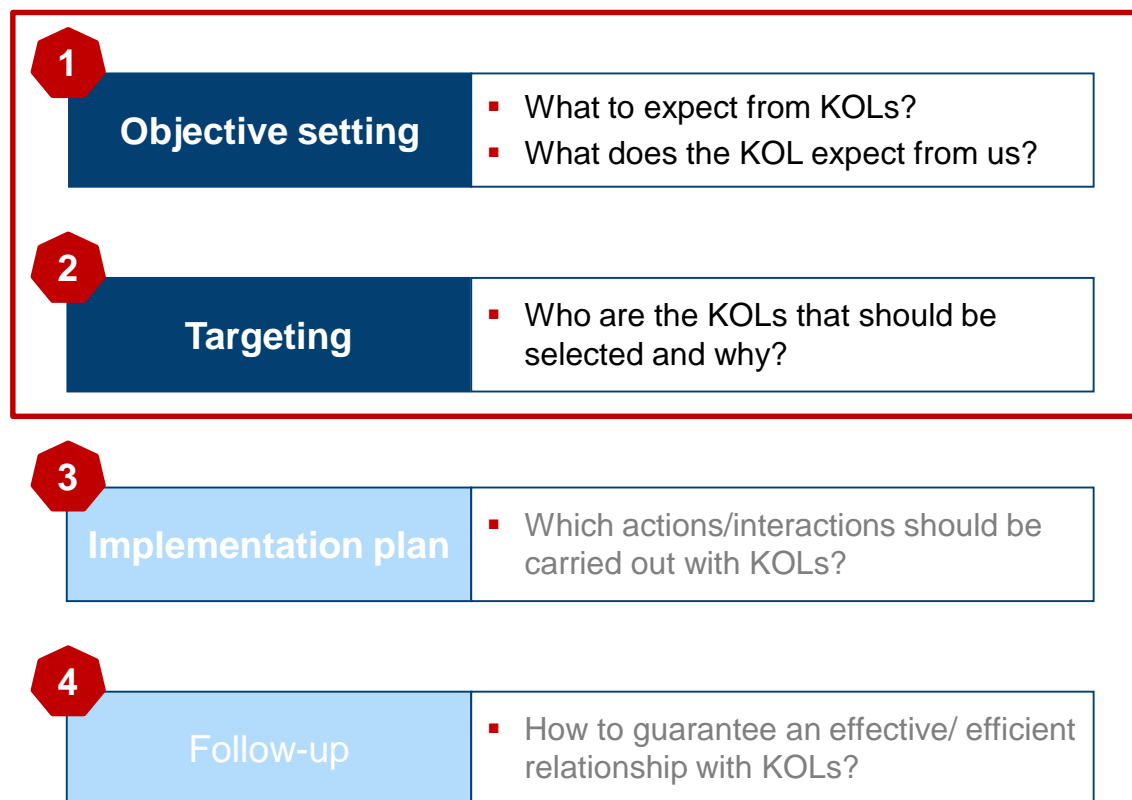
- Number of speeches delivered
- Number of articles authored
- Number of attendees
- Qualitative feedbacks of attendees

- Number of IIS<sup>1</sup> and / or company-sponsored clinical trials submitted / completed
- Number of investigators or patients included in company sponsored-clinical trials

**An effective collaboration with KOLs requires to follow a rigorous recruitment process that should be based on the gathering of accurate information**

**Recruitment & Management process of KOLs**

**The 4 key steps**



Recruitment

Management

- Relationships with KOLs should be defined according to the set objectives
- Then, the prospective KOLs should be profiled and targeted
- Once KOLs have been selected, their interactions with the pharma company and the activities they are expected to implement should be defined and formalized in an implementation plan
- The implementation of the plan should be carefully monitored with the help of KPIs (Key Performance Indicators) and of KEIs (Key Execution Indicators)

Before defining the activities to be carried out by KOLs, specific objectives, consistent with a global objective, have to be set for each of them

1

### Objective setting

*Partnerships with KOLs should be part of a global strategy, including also market access, medico-marketing and sales initiatives*

#### Global objective

Define precisely what is expected from the partnership with KOLs, in terms of direct or indirect benefits for the product under development or marketed by the pharma company



#### Specific objectives set by KOL

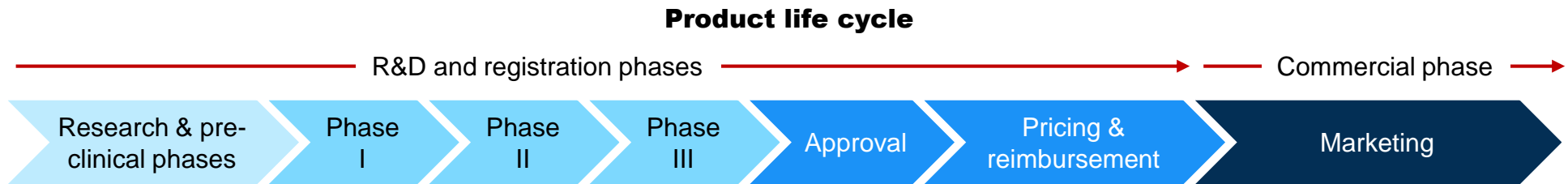


Define specifically what is expected from each KOL to support the product and what support the latter expects from the pharma company, on a professional stand point

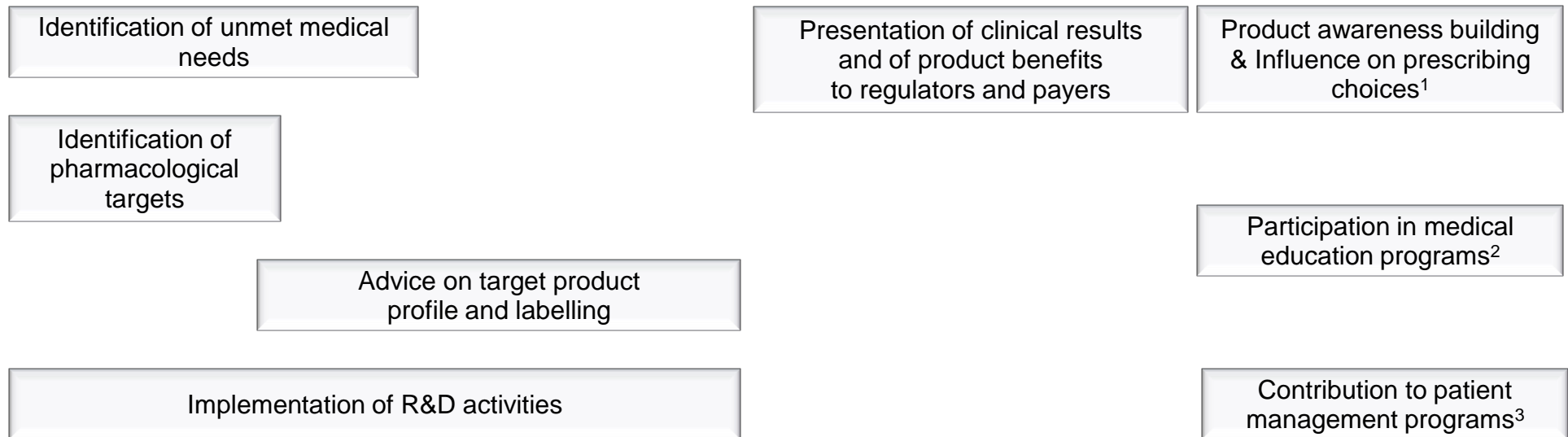


The objective of the KOL partnership and the corresponding activities will depend on where the product is positioned on its life cycle

**1 Examples of KOL roles according to the product life cycle**



**Examples of KOL roles**



The targeting phase should enable to identify the KOLs with whom a partnership should be beneficial and to understand their networks of influence

2

## KOLs targeting – Methodology (1/2)

### Key questions

### What to do?

#### Selection criteria

- What are the relevant selection criteria to be used considering the final objective?

- Review of relevant criteria (e.g. level of influence, scope of influence, scientific/media awareness, membership of a network, etc.)
- Selection of a limited number of relevant criteria

#### KOLs profiling

- What information should be collected?
- How to collect and analyze this information?

- Internal / external databases review to qualify KOLs
- Assessment of the number of publications, quotes, lectures during conferences and congresses, etc.

#### KOLs segmentation

- What is the degree of interest and the likely support of the KOL for the product?

- Mapping of preselected KOLs on a matrix according to the most relevant criteria
- Identification of KOLs' networks

#### KOLs selection

- Who are the KOLs that should be selected to partner with?
- For which kind of partnership?

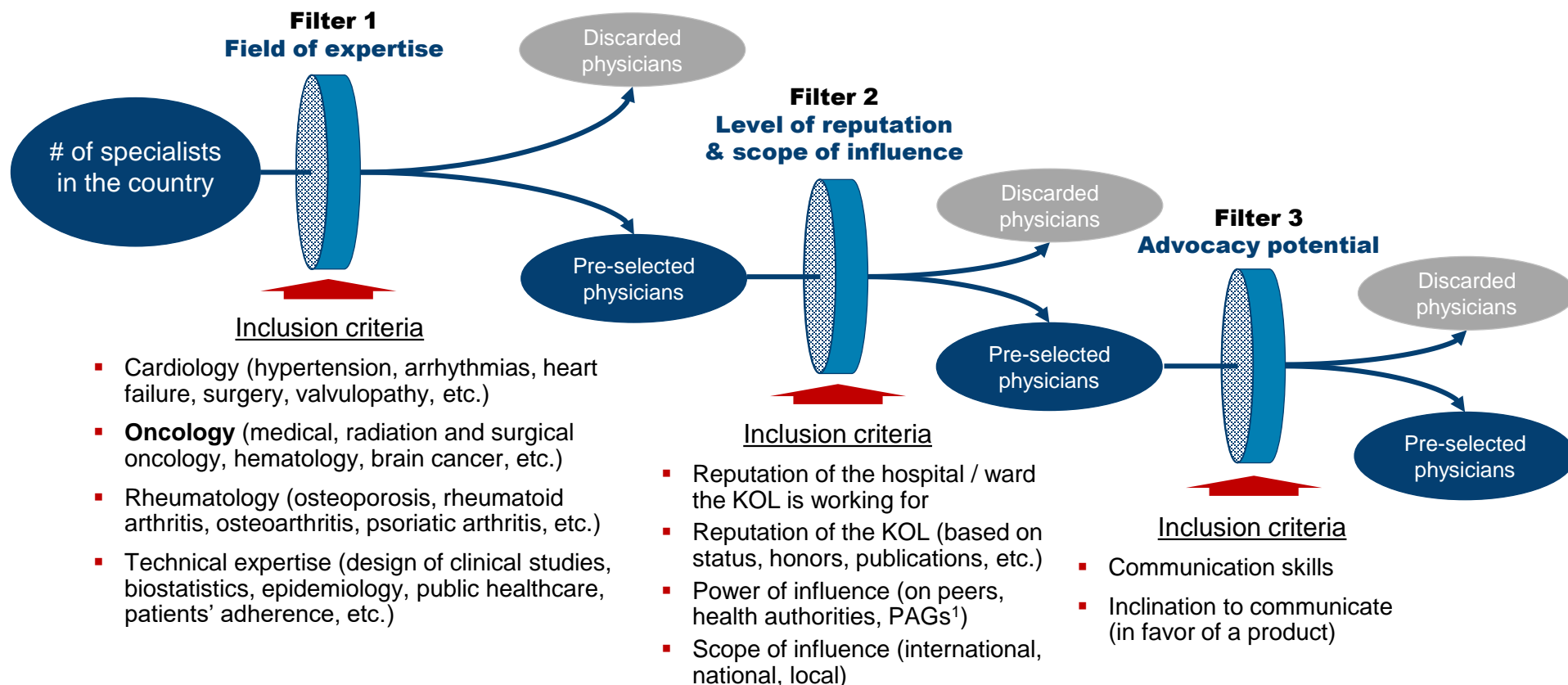
- Selection of KOLs
- Preliminary definition of the type of partnerships to be carried out with the targeted KOLs

Relevant selection criteria and gathering of accurate and reliable information about the KOL profile are of utmost importance to optimize the value of the partnership

2

## KOLs targeting – Methodology (2/2)

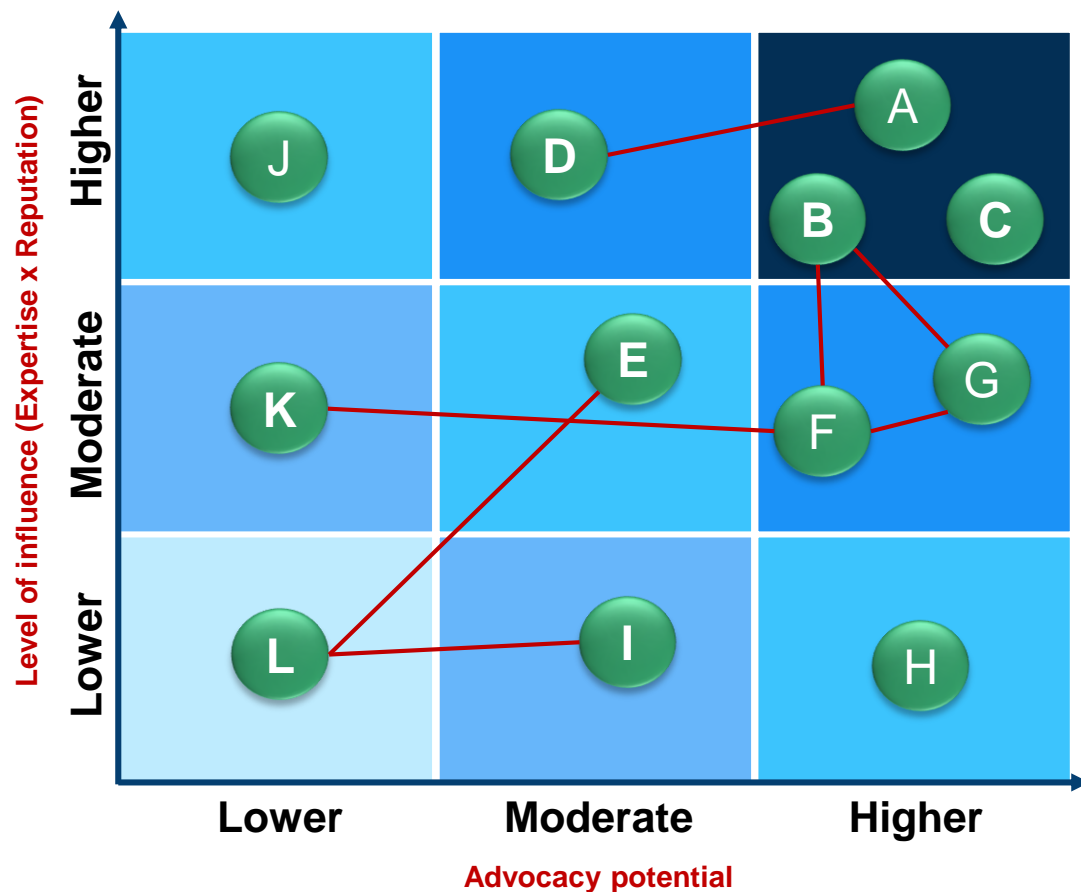
### Screening process (illustrative)



The proposed matrix is a useful tool to prioritize the candidate KOLs to partner with and to pre-define the type of partnerships that could be considered with them

2

## KOL targeting – Segmentation & selection



- The proposed matrix facilitates the final selection (targeting) of pre-selected KOLs based on their level of influence and their inclination to support the development and/or the use of the pharma company product
- The matrix helps to define the kind of partnerships to be set with the KOLs
- The prioritization of the targeted KOLs, should also take into account:
  - The life cycle of the product
  - The networks of influence of the KOLs

Priority 1
  Priority 2
  Priority 3
  Not a Priority

— Networks of influence amongst KOLs

**Qualification of KOLs should be documented with reliable data collected through desk research and field research (e.g. interviews of peers and of prospective KOLs)**

2

## How to qualify KOLs?

What data to collect?	How to collect data?	How to analyze data?
<ul style="list-style-type: none"> <li>▪ <b>Status</b> (e.g. head of medical department, professor, age, public vs. private practice, place(s) of practice)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Internet, direct search</li> </ul>	<ul style="list-style-type: none"> <li>▪ Being head of hospital and professor is a plus</li> </ul>
<ul style="list-style-type: none"> <li>▪ <b>Field of expertise/interest</b> in a therapeutic area, in a technique, etc.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Probing by MSL<sup>1</sup>, medical reps and other collaborators of the pharma company</li> </ul>	<ul style="list-style-type: none"> <li>▪ KOLs should express their field of interest over the long term and their expectations from a partnership with the pharma company</li> </ul>
<ul style="list-style-type: none"> <li>▪ <b>Level of reputation &amp; scope of influence</b></li> </ul>	<ul style="list-style-type: none"> <li>▪ Field research (e.g. peers, pharmacists interviews, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Internal or national level is preferable in general to local level (but it depends on the objective)</li> </ul>
<ul style="list-style-type: none"> <li>▪ <b>Communication skills</b></li> </ul>	<ul style="list-style-type: none"> <li>▪ Analysis of past performances</li> <li>▪ Interviews of peers</li> </ul>	<ul style="list-style-type: none"> <li>▪ Verbal communication (e.g. lectures, courses)</li> <li>▪ Written communication (e.g. articles, websites)</li> </ul>
<ul style="list-style-type: none"> <li>▪ <b>Type &amp; level of communication</b> <ul style="list-style-type: none"> <li>– # articles published (impact factor<sup>2</sup>, peer-/ non peer reviewed journals, position as an author...)</li> <li>– # of trainings p.a. (CME<sup>3</sup>)</li> <li>– Teaching activity at university</li> <li>– Presence on the Internet</li> <li>– # of lectures (congresses, round tables)</li> <li>– # of quotes by journalists in current year</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>▪ Review of scientific articles published (PubMed/Medline, Google scholar, Expertscape)</li> <li>▪ Probing by collaborators of the pharma company and peers interviews to evaluate trainings, teaching activities and lectures</li> <li>▪ Google searching for presence and quotes on the Internet</li> </ul>	<ul style="list-style-type: none"> <li>▪ The higher the impact factor is, the better</li> <li>▪ Each KOL should be ideally positioned as 1<sup>st</sup> or last author in articles</li> <li>▪ The higher the number of trainings, teaching seminars and lectures, the better</li> <li>▪ Perceived quality of articles, training, teaching and lectures should be assessed</li> </ul>
<ul style="list-style-type: none"> <li>▪ <b>Membership in learned societies</b> <ul style="list-style-type: none"> <li>– Title / position / activities</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>▪ On the website of the learned societies or by calling them</li> </ul>	<ul style="list-style-type: none"> <li>▪ Being a member of the management board is a plus</li> </ul>
<ul style="list-style-type: none"> <li>▪ <b>Inclination to partner with a pharma company and to support its products</b></li> </ul>	<ul style="list-style-type: none"> <li>▪ Probing by collaborators of the pharma company</li> </ul>	<ul style="list-style-type: none"> <li>▪ They should clearly express their interest in the product and the company...</li> <li>▪ ... and in the types of partnerships they are looking for</li> </ul>

**To convince KOLs to partner, it is important to take into account their expectations and to highlight the benefits they will draw from it, in terms of professional development**

**2****How to convince KOLs to partner?****What do they want?**

- Qualify a KOL to **design a partnership that will fulfill his professional expectations** (*simultaneously with that of the pharmaceutical company*):
  - Is the KOL yet a partner of the pharmaceutical company?
  - What has qualitatively and quantitatively his level of involvement been?
  - What has his feed-back from previous collaborations been?
  - What is his mid- to long-term professional ambition?
  - What does he expect from pharmaceutical companies in general, and specifically?
  - Is he looking for a long-term partnership?
  - Is he more inclined to enter into a “win-win” partnership or a “fee-for-service” transaction?

**What should be proposed?**

- Based on the knowledge and understanding of the KOL's professional expectations...
- ... propose ideas – to be discussed – of activities to be carried out through the partnership
- **Emphasize the benefits the KOL will draw** in terms of **personal awareness** and **competence development** through the partnership:
  - Increasing awareness and fame through publication of articles, interviews in media, presentations during congresses, lectures during medical meetings, etc.
  - Increasing reputation and extending influence by participating to scientific works (e.g. clinical trials)
  - Professional development through the access to recent information, to high education programs<sup>1</sup>, by working in new research/medical areas, etc.
  - Funding of Investigator Initiated Studies (IIS)

The KOL ID card is a practical tool which contains in one single page the most important information required to qualify and then recruit pre-selected KOLs

2

#### Tool to facilitate the recruitment process: KOL ID card

<b>KOL name</b>	(First name – surname)	<b>Medical status</b>	MD – head of medical department – professor of medicine, etc.	<b>Location</b>	Address & City
<b>Specialty</b>	(Oncology – cardiology, etc.)	<b>Medical setting</b>	Private hospital – public hospital – teaching hospital – private office	<b>Country</b>	

Specific objectives for the pharma company		•			
Specific benefits for the KOL		•			
<b>Items</b>		<b>Assessment<sup>1</sup></b>	<b>Facts / Rationale</b>		<b>Source</b>
<b>KOL Profile</b>	Field of expertise/interest in the therapeutic area	International - National - Local	•		
	Level of reputation	Low -Medium-High	•		
	Scope of influence	Low -Medium-High	•		
	Advocacy potential	Low -Medium-High	•		

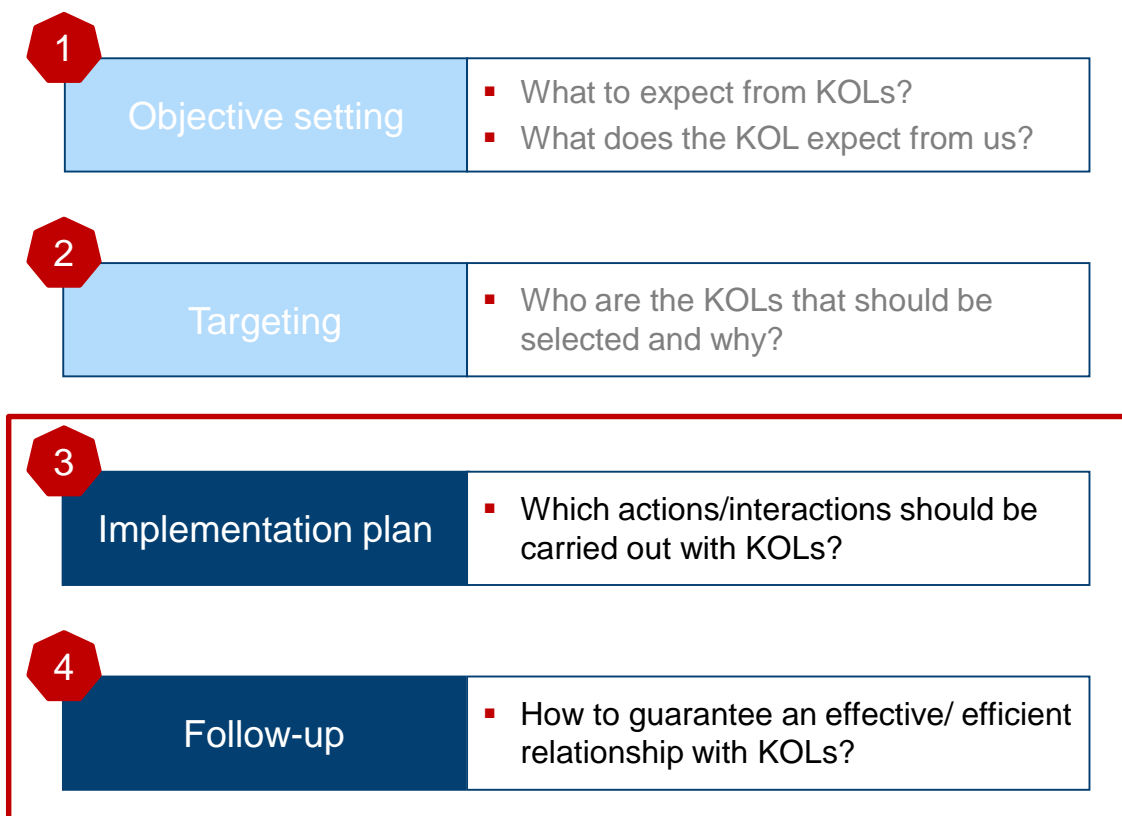
  

<b>Recommendations</b>	<b>Priority<sup>1</sup></b>	<b>Rationale</b>
<b>Medical department</b>	Low -Medium-High	•
<b>Final decision</b>		
<b>Selection: YES - NO</b>	<b>Rationale:</b>	

**An effective collaboration with KOLs requires to follow a rigorous recruitment process and to develop a precise action plan along with monitoring tools**

**Recruitment & Management process of KOLs**

**The 4 key steps**



Recruitment

Management

- Relationships with KOLs should be defined according to the set objectives
- Then, the prospective KOLs should be profiled and targeted
- Once KOLs have been selected, their interactions with the pharma company and the activities they are expected to implement should be defined and formalized in an implementation plan
- The implementation of the plan should be carefully monitored with the help of KPIs (Key Performance Indicators) and of KEIs (Key Execution Indicators)



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

3

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

#### Services proposed to KOLs (Illustrative)



#### Activities carried out by KOLs (Illustrative)



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

3

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

##### Article writing

- KOLs may support the pharmaceutical company's priorities by communicating in scientific journals, professional magazines or lay press regarding:
  - New medical approaches, new guidelines, patient management, etc. in a given therapeutic area, etc.)
  - The position of its products in the therapeutic strategy
- Perceived reliability by readers: **H**
- Number of exposed readers: **L to H**

##### Lectures during symposia

- While giving lectures, KOLs may accept to cover topics of interest for the company...
- ... and/or position their products vs. direct competitors or indirect therapeutic alternatives
- KOLs may also share their own experience as a prescriber of the company's products
- Perceived reliability by participants: **M**
- Number of exposed attendants: **L**

##### Press conference

- 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: **H**

##### Training of peers / CME<sup>1</sup>

- KOLs may communicate to their peers, to pharmacists, to nurses, etc., during training sessions regarding:
  - Medical topics of interest for the pharma
  - 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

**KOLs can be of great value through direct collaboration (by training, informing, giving advice, etc.) with medical, marketing and sales teams of the pharma company**

3

#### Potential value of KOL activities (2/2)

##### Participation to internal meetings

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

##### Promo material review

- 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...)

##### Advisory board member

- Advisory board meetings with KOLs should be preferred to individual meetings with KOLs when the objective is to:
  - Generate innovative ideas or concepts (brainstorming sessions)
  - Estimate key market trends (including stakeholders opinions and behaviors)
  - Obtain a consensual opinion regarding market environment, products development, marketing strategy, etc.

##### Participation to scientific studies

- 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

The development of a “KOL Partnership Plan” or K2P is a centerpiece to maximize the probability of success while partnering with KOLs

**3****KOL Partnership Plan (K2P) – Why?**

- The development of a clear – precise – concise and shared implementation plan, called “KOL Partnership Plan” or K2P – between KOLs and pharmaceutical companies – will ensure that:
  - The objectives of the collaboration is well understood and agreed upon
  - The reciprocal expectations are well defined and accepted
  - The respective commitments are fulfilled and in due time
- The preparation of an implementation plan increases the probability of success of the partnership over time...
- ... and minimizes the risks of mutual disappointments
- The KOL Partnership Plan (K2P) will facilitate the coordination and the communication across the pharmaceutical company and thus optimize synergies across market access, medical, marketing and sales departments

To build a useful and effective “KOL Partnership Plan”, it is recommended to follow the 5-step process proposed here-below

3

### KOL Partnership Plan (K2P) – How?



- Step 1: Design of templates that can be shared with the KOLs and the pharmaceutical company's collaborators (i.e. from market access, medical, marketing departments)
- Step 2: Filling up of the templates by the KOL Customer Manager assigned by the pharmaceutical company to the KOL (e.g. MSL) in coordination with the Medical Director and possibly with the Marketing Director<sup>1</sup>
- Step 3: Review and adjustment of the content of the K2P by the MSL with the KOL:
  - Objectives
  - Services proposed by the pharmaceutical company
  - Activities to be carried out by the KOL
  - Fees to be paid at a fair market value (if any)
  - Monitoring process of each service/activity
- Step 4: Follow up of the K2P:
  - Prepare the planned services/activities
  - Analyze the quality of execution of these services/activities
  - Reconsider – if not relevant anymore – planned services/activities
- Step 5: Assessment of the partnership:
  - Twice a year by the KOL Customer Manager and the KOL to measure the level of mutual satisfaction and decide about potential adjustments to be carried out
  - Once a year by a committee including: the Medical Director, the Marketing Director, the KOL Customer Manager, and possibly the General Manager, to evaluate the KOL partnership and decide about potential adjustments

The “KOL Partnership Plan” should include key information extracted from the KOL ID card<sup>1</sup>, specify the objectives of the partnership, its scope and duration

**3**

### KOL Partnership Plan (K2P) – Model: Introduction

<b>KOL name</b>	(First name – surname)	<b>Medical status</b>	MD – head of medical department – professor of medicine, etc.	<b>Medical setting</b>	Private clinic – private hospital – public hospital – teaching hospital
<b>Interest/ Expertise</b>	(e.g. Pulmonology, cardiology, etc.)	<b>Reputation/ Influence</b>	Private hospital – public hospital – teaching hospital – private office	<b>Advocacy potential</b>	Address & City & Country
<b>KOL Customer Manager</b>	(First name – surname – position in the company)	<b>Role</b>	(Describe briefly his role vis-a-vis the KOL)	<b>Coordination with...</b>	(Indicates the other collaborators whom to coordinate)
<b>Objectives of the partnership</b>	.				
<b>Specific scope of the partnership<sup>2</sup></b>	.	.	.	.	.
<b>Duration of the partnership</b>	<b>Starting date</b>		<b>Ending date</b>		
	.		.		

The “KOL Partnership Plan” should also describe the services proposed to the KOL and the activities the latter will carry out, as well as monitoring indicators



#### KOL Partnership Plan (K2P) – Model: Service/Activity Card<sup>1</sup>

Service or Activity #1	Pharma company objective	KOL objective	Key step description	Timing
.	.	.	.	.

Quality of execution Indicators		Expected impact Indicators		Comments
Expected	Achieved	Expected	Achieved	
.	.	.	.	
.	.	.	.	

**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 tool to monitor partnerships with KOLs

Pharma company's services	Key execution indicators (KEIs)	Key performance indicators (KPIs)
<ul style="list-style-type: none"> <li>Access to scientific information</li> <li>Organization of peer meetings with top international KOLs</li> <li>Technical support to publish articles</li> <li>Technical &amp; funding support to IIS<sup>1</sup></li> <li>Slide kits for training/teaching programs</li> <li>Ad hoc support on demand basis</li> </ul>	<ul style="list-style-type: none"> <li>Interest (10-point scale)</li> <li>Utility (10-point scale)</li> <li>Practicality (10-point scale)</li> <li>Implementation<sup>2</sup> (10-point scale)</li> </ul>	<ul style="list-style-type: none"> <li>Global level of satisfaction of KOLs (10-point scale)</li> <li>Inclination of KOLs to support the pharma company products: <ul style="list-style-type: none"> <li>Number of lectures / trainings / publications</li> <li>Quality/objectivity of messages conveyed to peers, pharmacists, patients, etc.</li> </ul> </li> <li>Increased level of KOLs awareness and reputation</li> <li>Increased level of products awareness and reputation</li> </ul>
KOLs' activities	Key execution indicators (KEIs)	Key performance indicators (KPIs)
<ul style="list-style-type: none"> <li>Lecture during symposia</li> <li>Training of peers</li> </ul>	<ul style="list-style-type: none"> <li>Interest (10-point scale)</li> <li>Utility (10-point scale)</li> <li>Practicality (10-point scale)</li> <li>Implementation<sup>2</sup> (10-point scale)</li> </ul>	<ul style="list-style-type: none"> <li>Global level of satisfaction of attendees (10-point scale)</li> <li>Inclination of attendees to support &amp; prescribe the product: <ul style="list-style-type: none"> <li>Number of lectures / trainings / publications</li> <li>Quality/objectivity of messages conveyed to peers, pharmacists, patients, etc.</li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>Article writing</li> <li>Press conference</li> </ul>	<ul style="list-style-type: none"> <li>Acceptance by recognized journals (scientific, medical, or in lay press, etc.)</li> <li>Post on highly regarded websites</li> <li>Number of journalists and quality of articles</li> </ul>	<ul style="list-style-type: none"> <li>Impact factor (for scientific/medical journals)</li> <li>Number of broadcasted issues for lay press</li> <li>Number of views / likes on Internet</li> <li>Contribution of content to support the product</li> </ul>
<ul style="list-style-type: none"> <li>Participation in scientific studies</li> </ul>	<ul style="list-style-type: none"> <li>Implementation (number of patients recruited, timing, cost vs. plan)</li> </ul>	<ul style="list-style-type: none"> <li>Publication of an article in a renowned scientific journal</li> <li>Impact of the publication on product reputation</li> </ul>



## 9 Recommendations *to Boost MSLs' Competence & Performance*

1. Clarify MSLs' roles and responsibilities to avoid confusion with medical representatives
2. Maintain a high scientific knowledge and understanding to guarantee high quality interactions and relationships with KOLs
4. MSLs' activities should be consistent with their ambition and their strategic priorities, as defined both at national and regional levels
5. Develop an Integrated Regional Strategic Plan<sup>1</sup> including a Medical section formalizing MSLs' ambition, strategic priorities and key activities, in line with marketing, sales, market access and adherence departments priorities
6. Define quantitative and qualitative metrics to monitor MSLs' activities and identify potential corrective measures to be introduced
7. Optimize MSLs' limited time by prioritizing their efforts and using new communication technologies, whenever relevant
8. Apply the KOL Partnership Model as follows:
  - a. Define clear and precise objectives for each of them
  - b. Build the relationship on the basis of an exchange of services rather than a fee-for-service deal
  - c. Ensure an open and transparent relationship
  - d. Make sure that the services provided to the KOL contribute to fulfill his needs and expectations
  - e. Don't ask KOLs to promote your products, which would affect his reputation and your company's one
  - f. Make the best use of the KOL limited time by organizing useful exchanges
  - g. Assign a KOL Customer Manager (e.g. a MSL) who will be the KOL-preferred contact point and who will ensure alignment and information sharing between all collaborators of your company in contact with him
9. Define internal guidelines and a control process to prevent any compliance issues that could damage the corporate reputation

## Smart Pharma Consulting Services – Optimizing the MSLs' performance (Case study)

Problem to be addressed

- The pharma company *MediSearch* has a team of **6 MSLs** specialized in **oncology**
- The Medical Affairs Director of the French subsidiary questions how MSLs could help improve *MediSearch's reputation* and the **perception** of its **products** by **oncologists**

Proposed approach

### 1. Kick-off meeting:

- Agreement on the **conditions** for **carrying out** the **mission** (adjustment of the approach, definition of the roles & responsibilities of each member of the project group)
- Precise definition of the **deliverables**

### 2. Interviews with 20 KOLs in oncology:

- Analysis of the **determinants** of **pharma companies' reputation** and of their **products' image** in oncology
- Identification of **pharma companies** whose **MSLs** are considered by oncologists as the “**best-in-class**”

### 3. Reflection workshop:

- Presentation & analysis of the **results of the interviews** conducted with the 20 KOLs
- Definition of “**best practices**” enabling MSLs to **strengthen** *MediSearch's corporate reputation* as well as the **image** of its products

### 4. Formalization of recommendations:

- **Drafting** of a **guide** of “**best practices**” (e.g. management of interactions with KOLs, activity planning, priority management, development of a culture of services, etc.)
- Proposal for a **strategic and operational plans model** for MSLs, including **quantitative** and **qualitative indicators** for **monitoring** their **activities**
- Setting up of a **training program** for MSLs



**The Brand Booster Program includes specific concepts, methods and tools which have been designed to develop Pharma Marketers competence and performance**

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**Context**

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- Over the past decade, **pharma marketing** functions have decreased in importance due to:
  - External factors:
    - **Health authorities** have raised regulatory **barriers** restricting the scope of possible marketing initiatives
    - **Healthcare professionals** have **reduced** the number of **interactions** with marketing and sales people and have become less and **less sensitive to operational<sup>1</sup> investment**
  - Internal factors:
    - **Marketing decisions** are more and more shifting from affiliates to headquarters, losing insight into their customers
    - **Marketers have** more and more **difficulties** in **differentiating** their brands
- **Smart Pharma Consulting has set up** the innovative **Brand Booster Program** to help **Marketers strengthen** their **competence**, **improve** the **performance** of their brands and become **Best-in-Class Pharma Marketers**

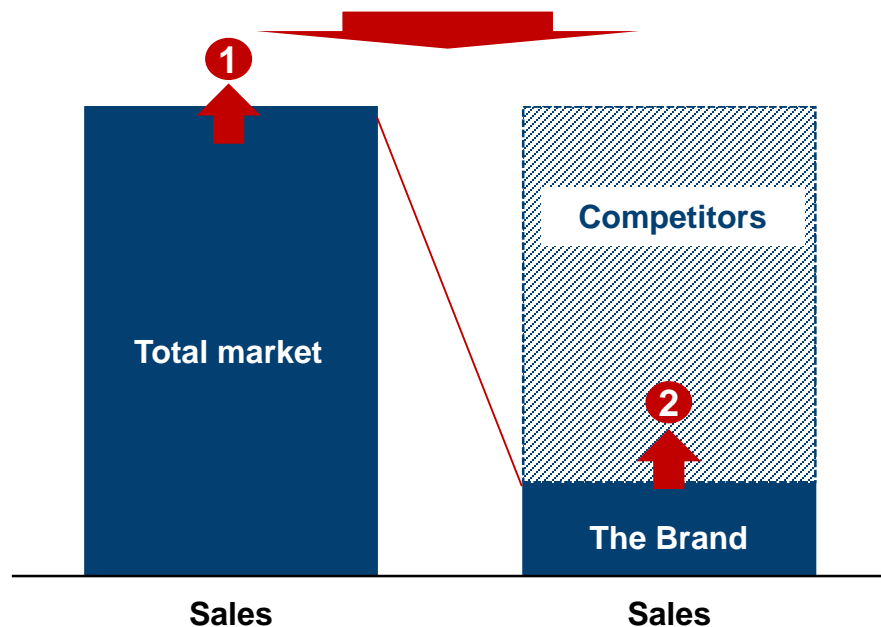
The Brand Booster Program helps Pharma Marketers optimize the performance of their brands by giving the priority to strategies that increase their market shares

## Objective

### Brand Performance Drivers

**1** Increase market size

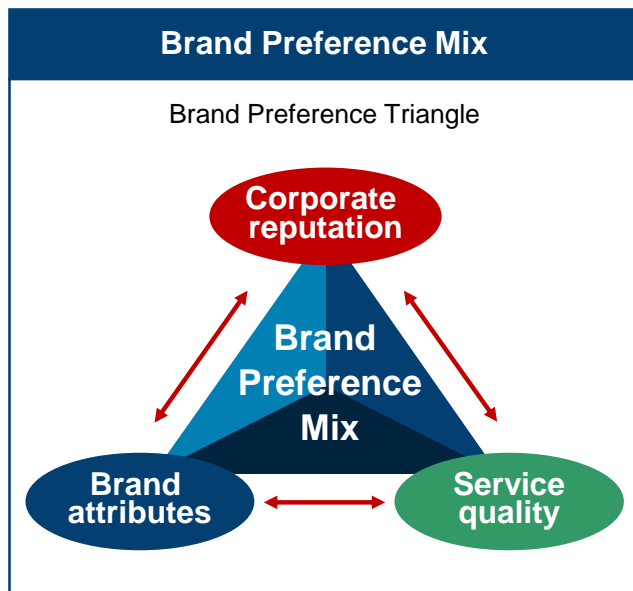
**2** Increase market share



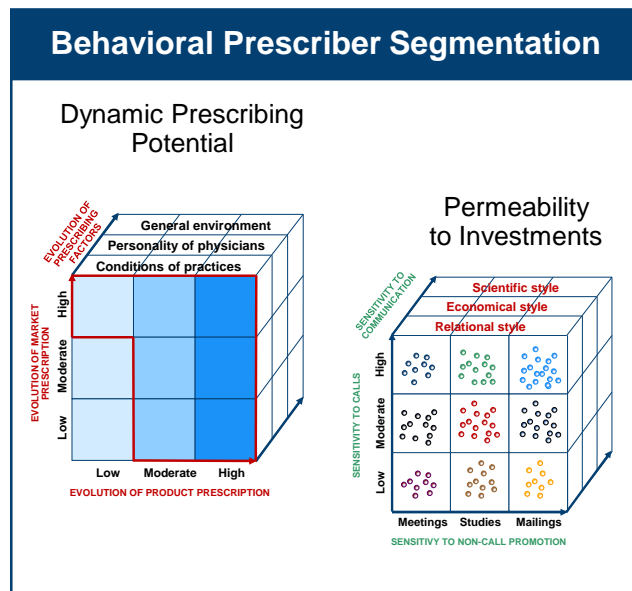
- The slowdown in the pharma market growth leads pharma companies to focus on gaining market shares
- The **Brand Booster Program (BBP)**, which has been developed to help pharma companies achieve this objective, is based on three frameworks:
  - The **Brand Preference Mix (BPM)** driving market share gain
  - The **Behavioral Prescriber Segmentation (BPS)**, which improves the efficacy and efficiency of marketing investments
  - The **Individual Prescriber Plan (IPP)**, which formalizes tailor-made operational<sup>1</sup> activities for an optimal efficiency
- The **Brand Booster Program** guarantees consistency between market reality and marketing activities to be implemented to boost brands sales

The Brand Booster Program relies on three simple, logical and complementary frameworks that can be advantageously combined for a faster and higher impact

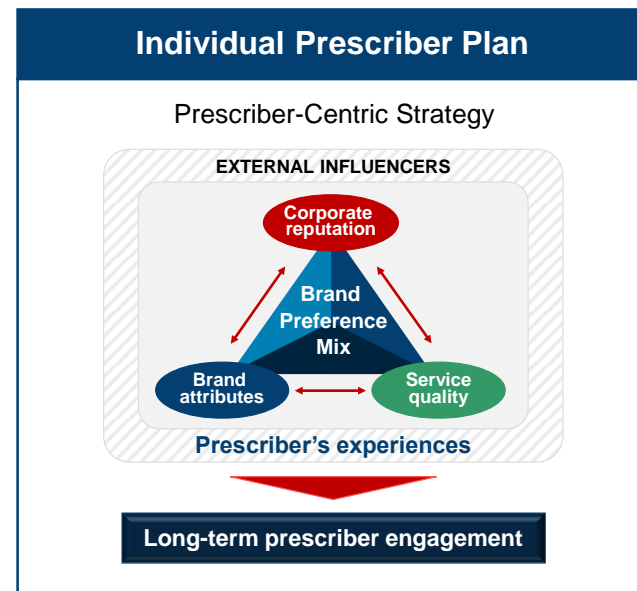
## Executive Summary – Frameworks



- The share of brand prescription is driven by physicians' preference level
- This level can be enhanced by acting on the Brand Preference Mix (BPM), i.e. brand attributes, service quality and corporate reputation



- The Behavioral Prescriber Segmentation is built on 3 dimensions:
  - Factors that drive the dynamics of prescribers' prescriptions<sup>1</sup>
  - Prescribers' personalities
  - Prescribers' permeability to investments<sup>2</sup>



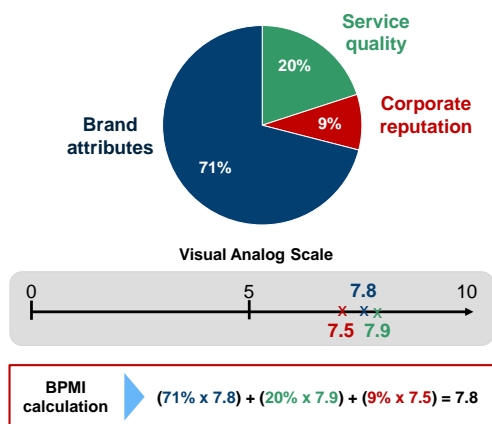
- The cornerstone of the Individual Prescriber Plan is the individual prescriber-centric strategy
- This strategy is about building positive experience with the company, the brand and the services to boost preference

The tools supporting the Brand Booster Program are pragmatic and user-friendly, which facilitates their use by pharma marketers

## Executive Summary – Tools

### Brand Preference Mix

Brand Preference Mix Index



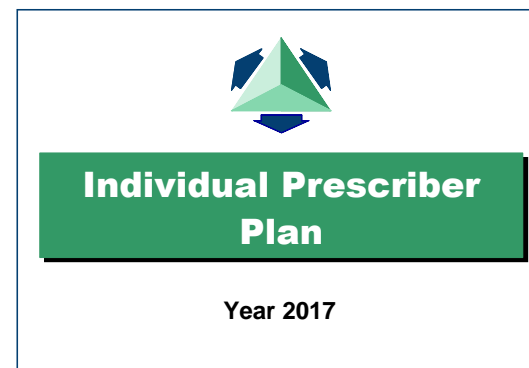
### Behavioral Prescriber Segmentation

Individual Prescriber Portrait

Physicians	Evolution Market/Brand	Permeability to calls/marketing	Personality dominance
A	High/Moderate	High/Mailings	Relational
B	Moderate/High	High/Meetings	Scientific
C	High/High	Low/Studies	Scientific
D	Moderate/Moderate	High/Meetings	Economic
E	Low/Low	High/Meetings	Relational

### Individual Prescriber Plan

Prescriber-Centric Brand Plan



- The Brand Preference Mix Index is a practical measurement tool that can be used at national level, at hospital/department level, or at individual prescriber level through face-to-face or phone interviews

- The Behavioral Prescriber Segmentation tracks by prescriber:
  - The evolution of its prescriptions
  - The dominant traits of its personality
  - Its permeability (accessibility + sensitivity) to operational<sup>1</sup> investments

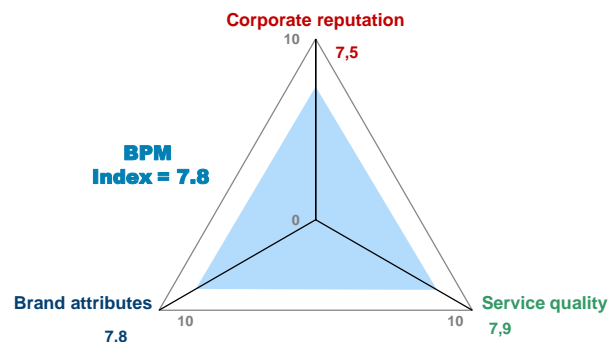
- The Individual Prescriber Plan describes, on a brand and client basis:
  - Qualitative & quantitative objectives
  - Strategic levers & corresponding medico-marketing-sales initiatives to meet these objectives
  - Monitoring tools (KEIs<sup>2</sup> – KPIs<sup>3</sup>)

The Brand Booster Program helps to determine the optimal level and nature (channel, message, tone) of operational<sup>1</sup> resources to be allocated per physician

## Executive Summary – Benefits

### Brand Preference Mix

Brand Preference Map



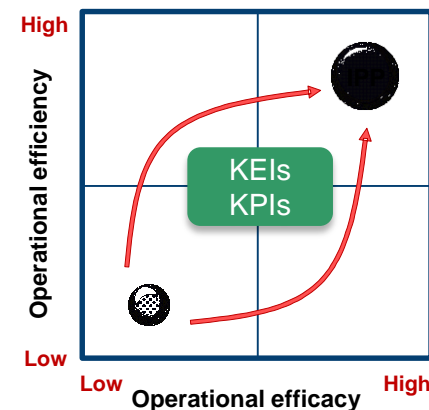
### Behavioral Prescriber Segmentation

Individual Prescriber Operational<sup>1</sup> Mix

Physicians	# of Calls	# of Meetings	# of Studies	# of Mailings	Messages & Style
A	12	2	0	4	Dialogue Services
B	8	5	0	0	Scientific
C	6	1	2	0	Scientific
D	6	2	1	1	Economic
E	4	1	0	0	Dialogue Services

### Individual Prescriber Plan

Operational Performance Matrix



- In addition to providing the necessary data to measure the Brand Preference Mix Index, interviews will provide information to identify the strategic levers and the key initiatives to implement to reinforce the three dimensions of the Brand Preference Mix

- The Behavioral Prescriber Segmentation provides a behavioral portrait for each prescriber, allowing a more effective/efficient targeting and a customized allocation of operational<sup>1</sup> resources for each prescriber

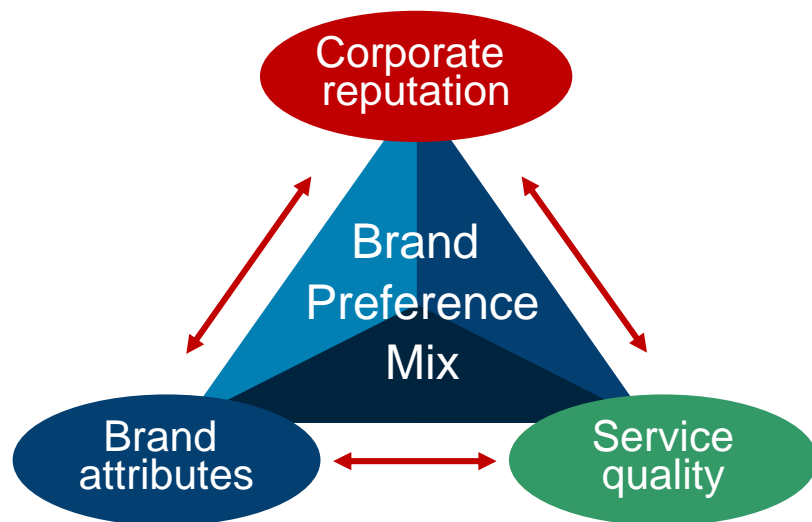
- The Individual Prescriber Plan improves operational efficacy/efficiency through:
  - A rigorous planning of operational activities
  - A systematic monitoring of the execution and impact of activities<sup>1</sup> with specific indicators (KEIs<sup>2</sup> – KPIs<sup>3</sup>)



**The Brand Preference Mix determines the key drivers that can be activated to enhance prescribers preference and ensure maximum market share**

**Framework (1/2)**

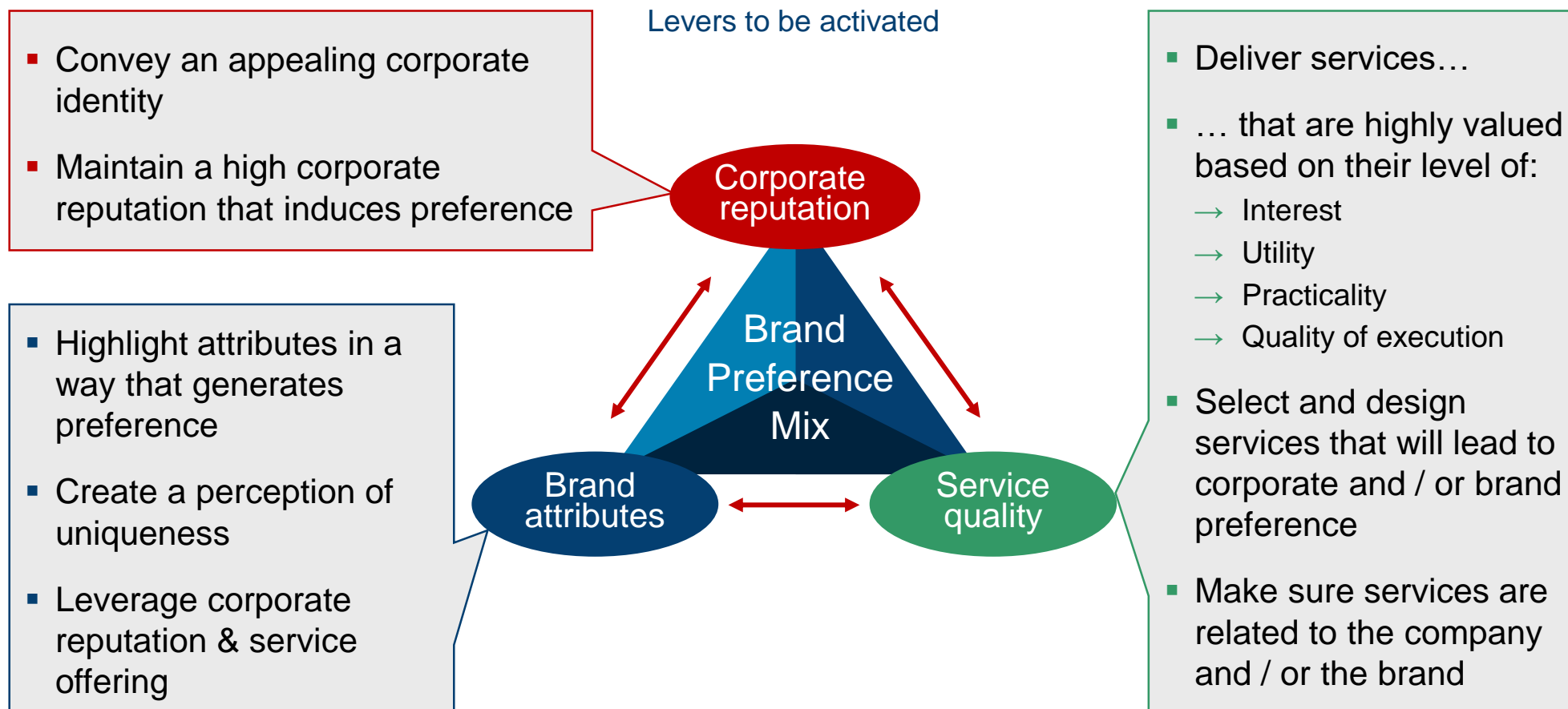
Brand Preference Triangle



- As the great majority of prescribers use several brands for a given pathology:
  - The challenge for pharma companies is to increase their preference for their brands, to get a bigger share of their prescriptions (vs. competitors)
  - Strengthening the preference of a prescriber for a brand must go beyond securing brand loyalty only
- To reinforce brand preference, pharma companies should optimize their Brand Preference Mix:
  - The perceived value of their brand (product) attributes
  - The perceived quality of the services they offer and deliver to physicians
  - Their corporate reputation
- The links between the three components of the Brand Preference Mix should be well established in the mind of prescribers

**To boost the preference of physicians for their marketed brands, Pharma Marketers can leverage the three components of their Brand Preference Mix (BPM)**

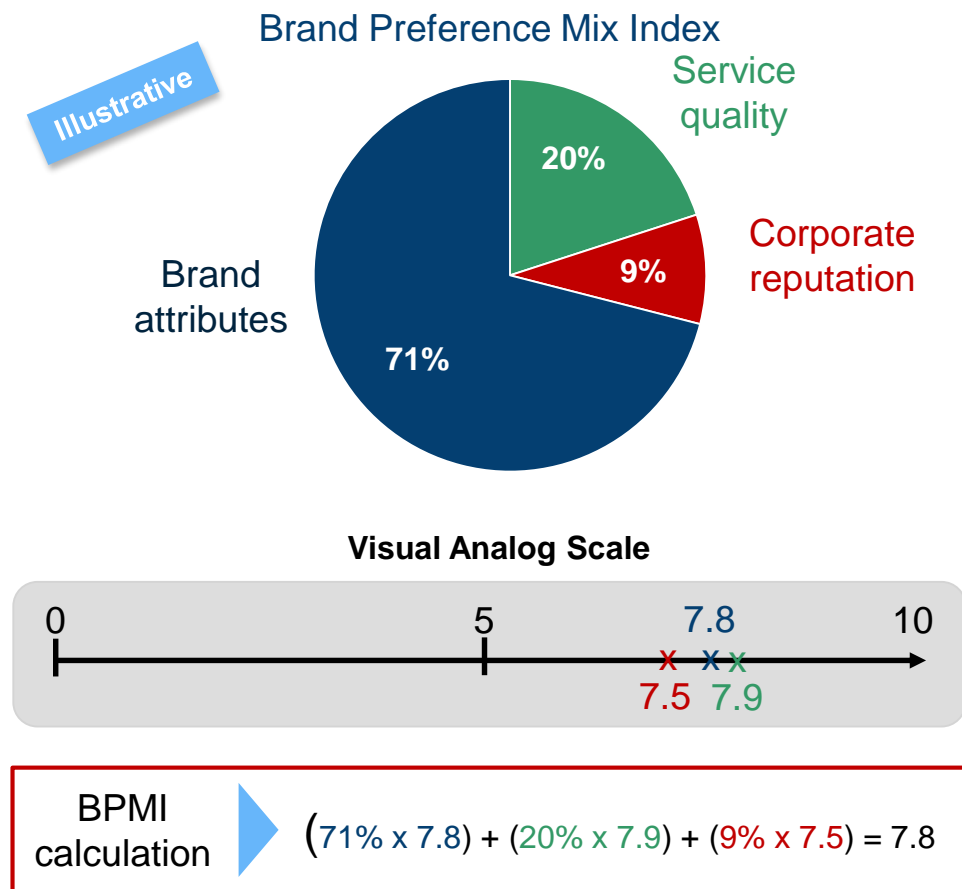
**Framework (2/2)**



Sources: "Building prescriber loyalty", J.-M. Peny et al., SCRIP Magazine, September 1993 – Smart Pharma Consulting

The Brand Preference Mix Index (BPMI) enables to evaluate the brand performance on each of its preference components, over time and compared to its competitors

**Tool**



- The Brand Preference Mix Index (BPMI) is a measurement tool that takes into account:
  - The relative importance of each BPM component (i.e. corporate reputation, brand attributes and associated service quality) per brand
  - The score of the brand, on a 10-point scale, for each of its preference components
- The BPMI can be defined per customer<sup>1</sup>, per indication, per form, etc.
- The BPMI scores the customer perception at a given point in time, making possible to track the evolution of this perception over time and to compare it to competitors, considering:
  - External events (i.e. related to health authorities, competitors and customers' behaviors)
  - Internal events (i.e. related to operational activities<sup>2</sup>, quality of services offered, communication strategy, etc.)

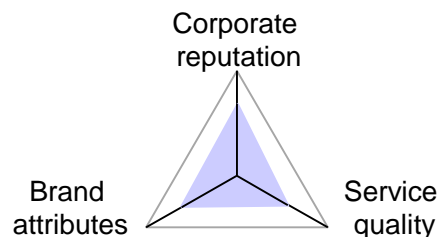
Sources: "Building prescriber loyalty", J.-M. Peny et al., SCRIP Magazine, September 1993 – Smart Pharma Consulting

<sup>1</sup> Physicians, patients, pharmacists, nurses, payers, health authorities, etc.  
<sup>2</sup> Medico-marketing-sales

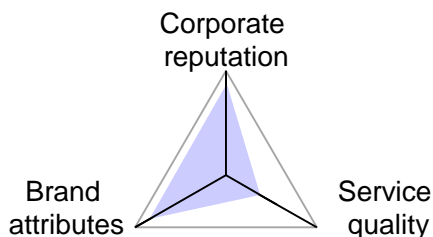
**The BPM Index can be assessed at national level through market research studies and at hospital/department and individual levels through interviews by sales forces**

### Method (1/2)

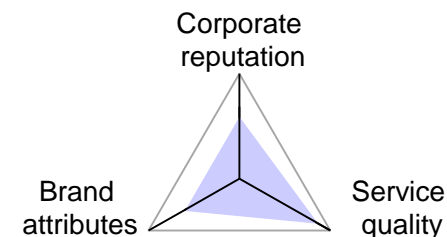
#### National level



#### Hospital / Department level



#### Prescriber level



- The Brand Preference Mix Index (BPM Index) should be measured, at the national level, through face-to-face or phone interviews by an external agency
- The number of interviewees should be approximately 30 for specialists and 60 for GPs, in medium to large markets such as France, Germany, Italy, Spain, the UK, etc.
- The rationale behind the scores obtained for each dimension of the BPM Index must be investigated

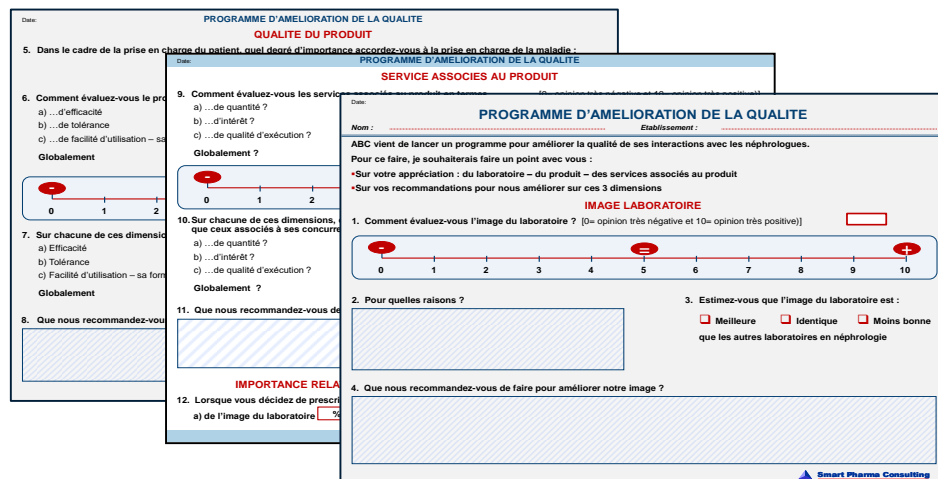
- The BPM Index can also be measured at a hospital or a hospital department level (i.e. cardiology, oncology, etc.) through interviews carried out by the field forces (i.e. medical reps, KAMs, MSLs, etc.) of pharmaceutical companies<sup>1</sup>
- Interviews can be either concentrated on key hospitals and/or departments or carried out on all those that have been targeted
- The reasons that support the evaluation should be captured

- The BPM Index should be measured at the level of each targeted prescriber through face-to-face interviews carried out by medical reps or other field force collaborators
- Prescribers should be interviewed at least once a year, but ideally twice a year
- Medical reps should carefully and precisely identify the reasons that motivate the marks granted by the prescribers for their brands and those of their most important competitors

Med reps can monitor the brand performance with the “Brand Preference Mix Index” while calling upon their targeted physicians and thus, fine-tune their activities

### Method (2/2)

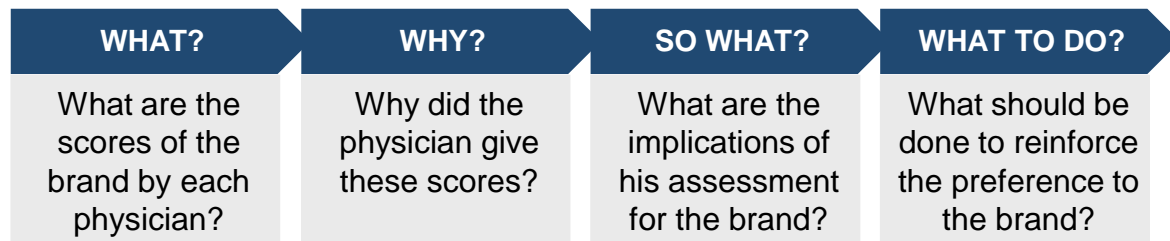
#### Assessment guide for medical reps



The form is titled 'PROGRAMME D'AMELIORATION DE LA QUALITE' and is divided into several sections. The first section, 'QUALITE DU PRODUIT', asks for a global evaluation of the product. The second section, 'SERVICE ASSOCIES AU PRODUIT', asks for a global evaluation of the service. The third section, 'IMAGE LABORATOIRE', asks for an evaluation of the laboratory's image. The fourth section, 'IMPORTANCE RELATIVE', asks for a recommendation on the relative importance of the brand. The form includes various checkboxes and a scale from 0 to 10 for each evaluation.

- Recent experiences have shown that:
  - >95% of physicians accept to be questioned on the three components of the BPM
  - >80% of physicians consider that the BPM approach conveys a positive image
  - >85% of medical reps say that the BPM helps improve their insight into physicians
- Once physicians have evaluated the brand with the BPM, they are asked:
  - What is the rationale supporting these scores?
  - What should be done to raise their preference to the brand?
- Then, med reps can fine-tune their messages, their activities, physician by physician, based on the feedback
- The collected information should be shared with marketers who will define specific initiatives to reinforce prescribers' preference to the brand

#### From observation to decision: The 4 Ws approach

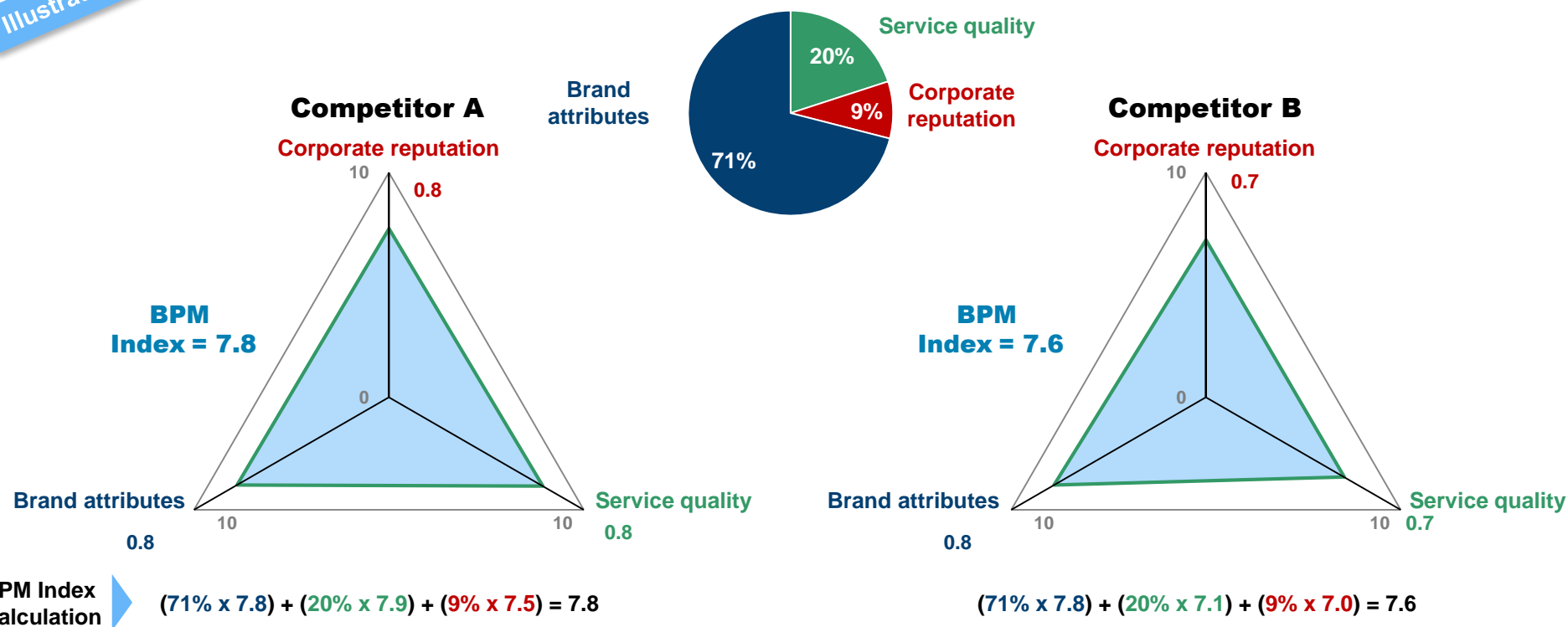


The Brand Preference Mix Index permits to track the performance of each brand on the three dimensions of the Brand Preference Mix, down to the individual prescriber

**Benefits (1/2)**

Illustrative

Brand Preference Map

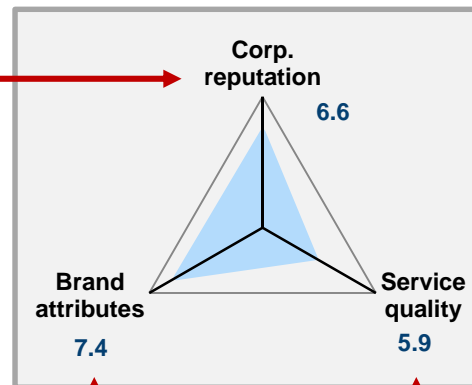
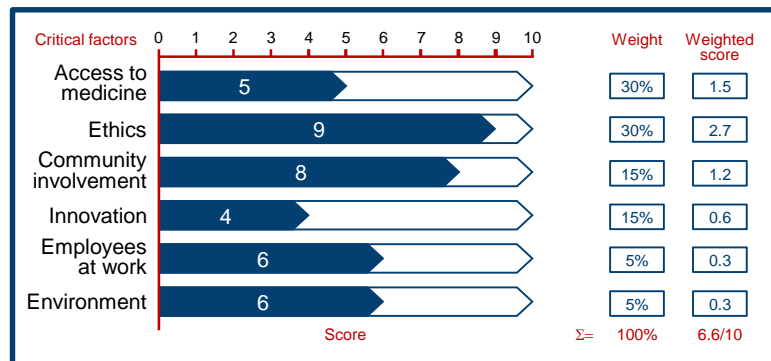


Number of respondents: 31 hospital gastroenterologists

It is possible to identify the rationale behind the scores of the brands for each component of the Brand Preference Mix and then to find solutions to improve them

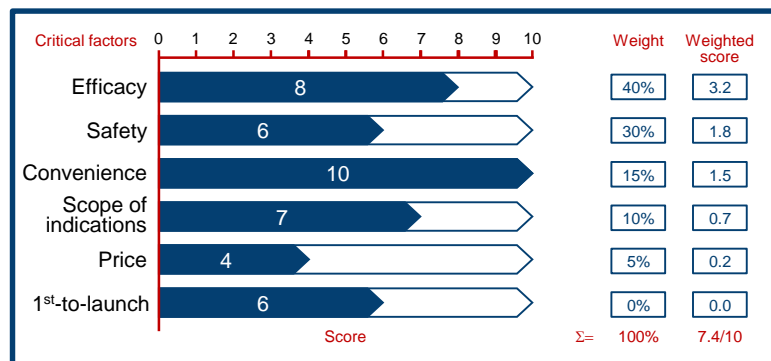
## Benefits (2/2)

### 1. Corporate Reputation Score

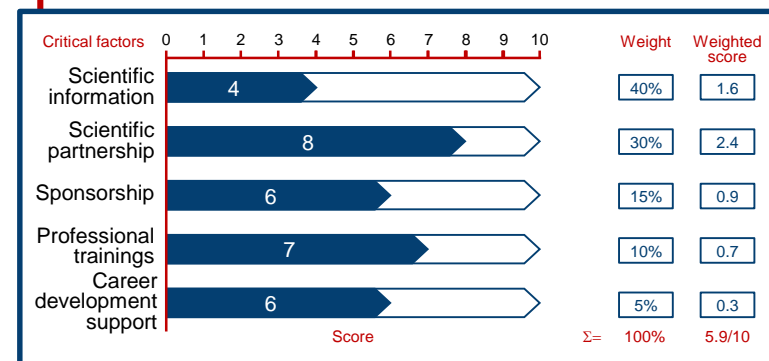


1. The Corporate reputation score is strongly driven by CSR<sup>1</sup> and scientific commitment which requires regular and well-structured communication to prescribers
2. The Service quality score depends mainly on the quality of scientific information, for which medical reps remain an important communication channel
3. The Brand attributes score depends on different components according to the product type (OTC vs. Rx), its lifecycle stage and its reimbursement status

### 3. Brand Attributes Score



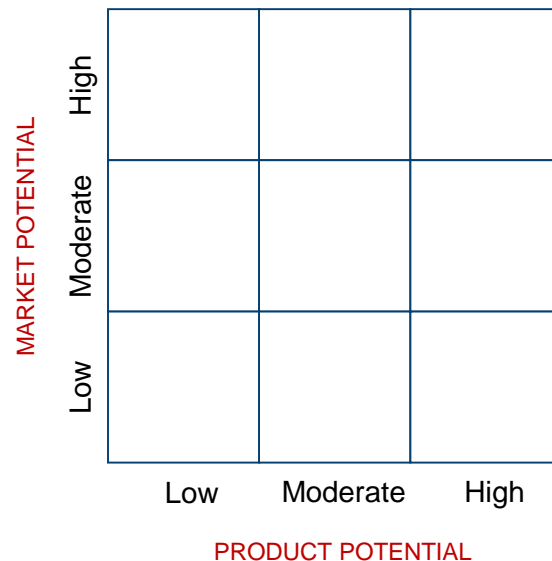
### 2. Service Quality Score



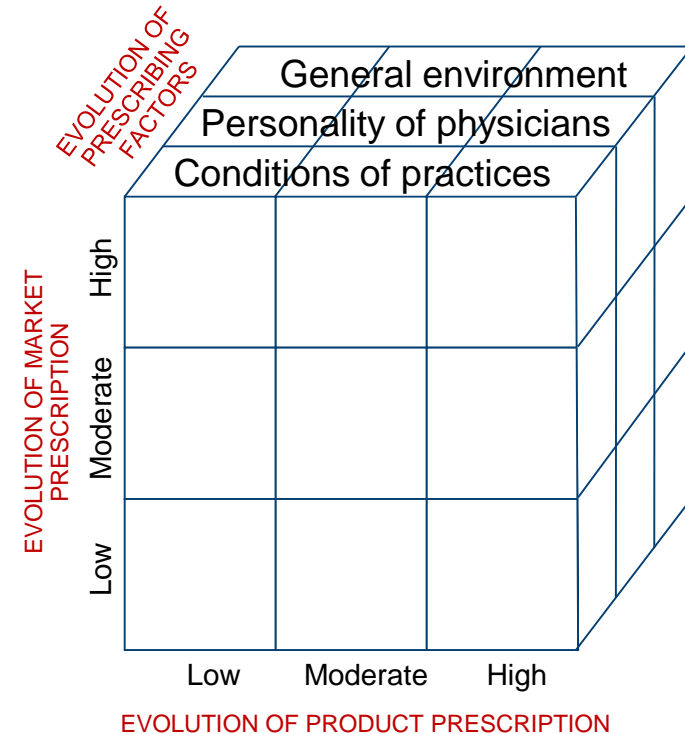
The replacement of a static profiling of physicians by a dynamic one, enables to capture more relevant and accurate insights regarding their prescribing potential

**Framework (1/2)**

Static physician segmentation



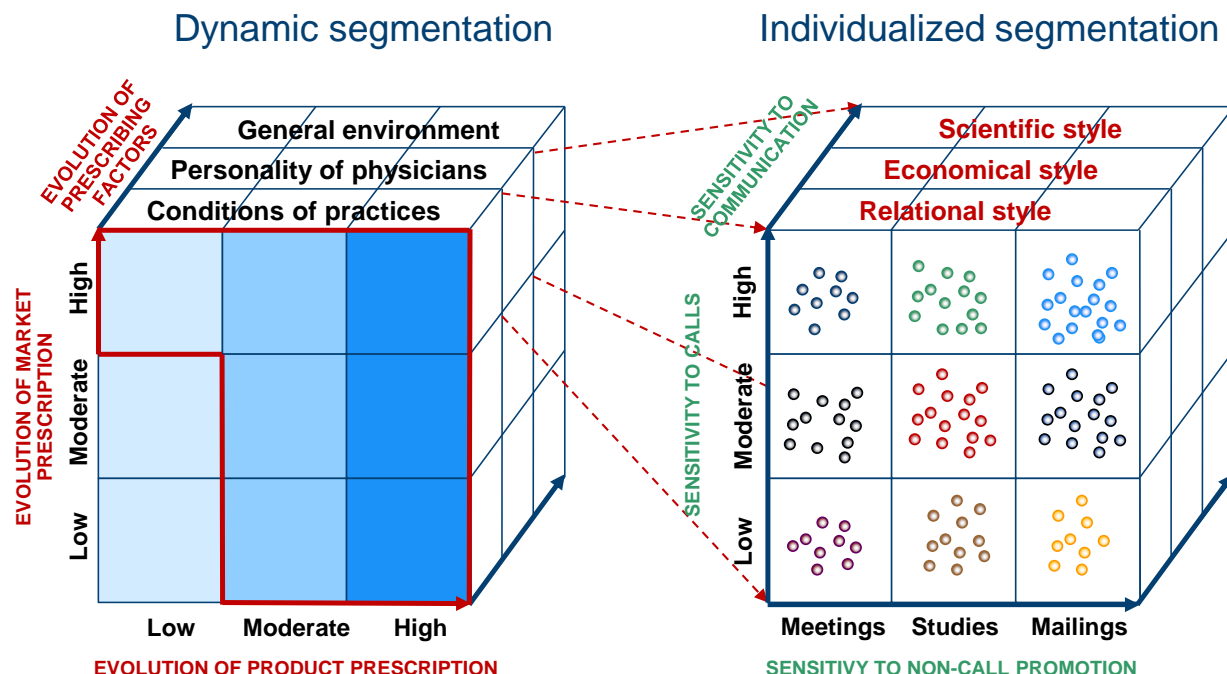
Dynamic physician segmentation





The Behavioral Prescriber Segmentation is based on the dynamic assessment of the prescription potential and on the permeability to investment per individual prescriber

### Framework (2/2)



\* Key factors that determine the evolution of market<sup>2</sup> and brand prescriptions by physician

- Environment (e.g. patient flow, regulations, public health initiatives, Sick Funds decisions, reimbursement, drug prices, influencers such as Key Opinion Leaders, etc.)
- Personality (e.g. innovative, conservative or resistant profile, willingness to try new therapeutic protocols, new products, etc.)
- Medical practice (e.g. habits of prescriptions, involvement in clinical studies, compliance with guidelines, etc.)

- The Behavioral Prescriber Segmentation (BPS) optimizes the efficacy and efficiency of the operational<sup>1</sup> investments targeted at each prescriber
- The BPS consists in identifying:
  - The evolution of market<sup>2</sup> and brand prescriptions by physician
  - The key factors determining that evolution (environment, personality and medical practice)\*
  - The permeability (accessibility and sensitivity) to operational channels and activities such as:
    - Face-to-face calls
    - Other operational initiatives (including digital ones)
  - The personality dominance of each physician (relational, economic, scientific)

**The Individual Prescriber Portrait keeps a track record of sales potential dynamics, permeability to operational<sup>1</sup> activities and personality dominance for each prescriber**

## Tool

### Individual Prescriber Portrait

Physicians	Evolution Market/Brand	Permeability to calls/marketing <sup>2</sup>	Personality dominance
A	High/ Moderate	High/Mailings	Relational
B	Moderate/ High	High/Meetings	Scientific
C	High/High	Low/Studies	Scientific
D	Moderate/ Moderate	High/Meetings	Economic
E	Low/Low	High/Meetings	Relational

- To implement the Behavioral Prescriber Segmentation, it is necessary to set up a process to collect, store, analyze and retrieve three sets of data for each prescriber:
  - The evolution (negative, neutral, positive) of their prescription level:
    - Market dynamics (the brand + its competitors)
    - The brand dynamics
  - Their permeability (accessibility and sensitivity) to operations<sup>1</sup>:
    - Face-to-face calls
    - Other operational channels, including digital ones (e.g. remote e-detailing, e-mailing, e-meetings, websites, etc.)
  - The dominant trait of their personality (relational, scientific, economic)
- Medical reps and other collaborators in contact with prescribers should be involved in the collection of those data, which should be updated on an ongoing basis
- These data will define the “Individual Prescriber Portrait” that will then be used to set the optimal level and mix of operational activities for each prescriber

The level and mix of operational<sup>1</sup> activities for each prescriber depend on his specific profile which should be mainly documented by medical representatives<sup>2</sup>

### Method

#### Profiling

- Assessment of Market/Product dynamics evolution per prescriber by med reps on a regular basis:
  - Observation and probing of physicians...
  - ... and of other relevant healthcare professionals
- Identification of the key drivers that influence the prescribing dynamics of each physician (environment, personality, medical practice)
- Identification of each physician's permeability (access & sensitivity) to operational channels & activities
- Definition of each physician's personality dominance (relational, scientific, economic)

#### Segmentation

- Segmentation of physicians based on the following individual characteristics:
  - Market dynamics
  - Product (brand) dynamics
  - Factors that drive these dynamics
  - Permeability to medico-marketing-sales activities, including the preferred channels
  - Drivers related to the dominant traits of their personality that will contribute to influence their prescribing choices:
    - Scientific drivers
    - Economic drivers
    - Relational drivers

#### Adjustment

- Determination of the magnitude of the operational effort per prescriber considering:
  - The prescription dynamics for a given indication (the Market) and for the pharmaceutical company product (the Brand)
  - The degree of operational permeability to operational channels (including digital ones) and to operational activities
- Definition of the communication messages based on:
  - The market potential (patient flow and diagnosis rate)
  - The prescribing habits
  - The reasons that determine the product choice

**The Behavioral Prescriber Segmentation permits to adjust medico-marketing and sales activities to the respective sensitivity and personality of each physician**

### Benefits

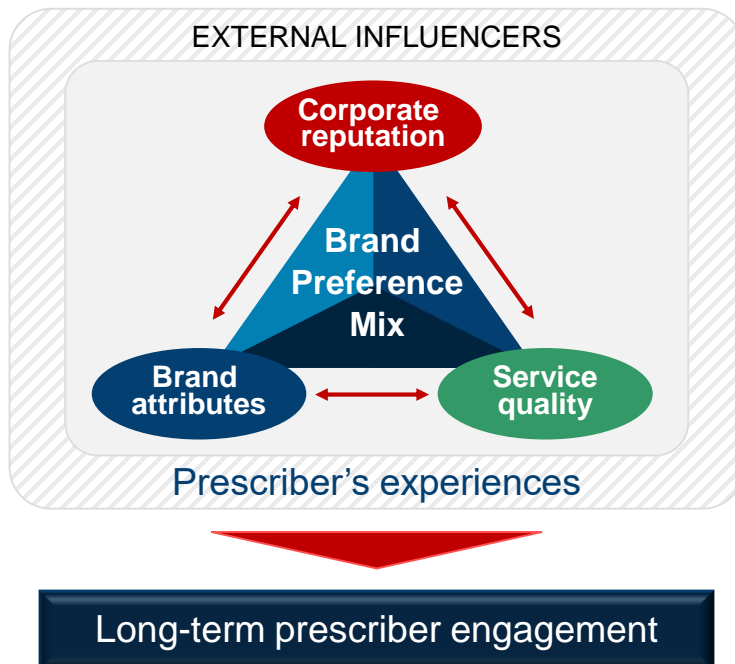
Physicians	Individual Prescriber Portrait			Individual Prescriber Operational Mix				Messages & Style
	Evolution Market/Brand	Permeability to calls/marketing	Personality dominance	# of Calls	# of Meetings	# of Studies	# of Mailings	
<b>A</b>	High/Moderate	High/Mailings	Relational	12	2	0	4	Dialogue Services
<b>B</b>	Moderate/High	High/Meetings	Scientific	8	5	0	0	Scientific
<b>C</b>	High/High	Low/Studies	Scientific	6	1	2	0	Scientific
<b>D</b>	Moderate/Moderate	High/Meetings	Economic	6	2	1	1	Economic
<b>E</b>	Low/Low	High/Meetings	Relational	4	1	0	0	Dialogue Services

- The Behavioral Prescriber Segmentation (BPS) offers pharmaceutical companies a more reliable estimate of individual prescribers' prescription potential than conventional approaches do
- The BPS also helps to acquire a better understanding of factors driving prescribers' brand preference
- Thus, by implementing the BPS, pharmaceutical companies can determine, for each prescriber, the operational actions likely to be the most:
  - Effective (message content and style of communication)
  - and
  - Efficient (level and nature of efforts)

## The Individual Prescriber Plan is essential to structure and formalize a Prescriber-Centric Strategy to secure Brand Preference and long-term engagement

### Framework

#### Prescriber-Centric Strategy



- The Individual Prescriber Plan (IPP) is built around prescribers who represent the most important customer category for Rx-driven brands of pharma companies
- Depending on the type of products, physicians, nurses, pharmacists and even patients can all be considered as “prescribers”
- External influencers, such as health authorities, politicians, sick funds, private health insurance, patient advocacy groups, professional associations, pharmaceutical companies, key opinion leaders, etc., may also play an essential role by modifying the behavior of prescribers
- Prescriber-centricity requires going that extra mile to please the prescriber and ensure that he enjoys the experience of being:
  - A prescriber of the company and of its brand(s)
  - A beneficiary of the associated services
- Positive experiences are essential to create sustainable prescriber preference to brands and to induce their long-term engagement (active loyalty)

## The Individual Prescriber Plan makes it possible to set objectives by individual prescriber and define the appropriate operational activities to meet these objectives

### Tool

#### Prescriber-Centric Brand Plan

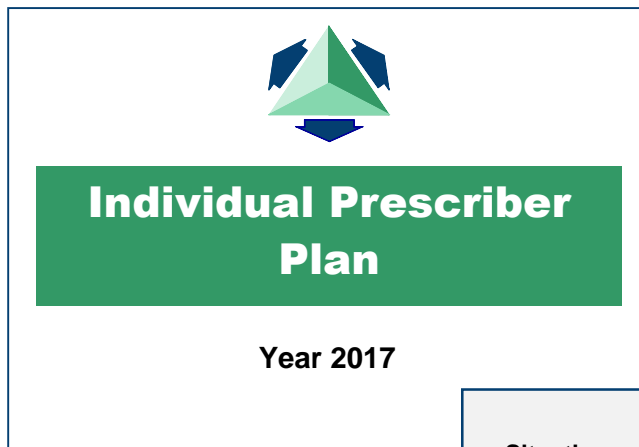


Table of Contents
<b>Situation analysis by prescriber</b>
– Evolution of market/brand prescription
– Key factors determining that evolution
– Permeability (accessibility and sensitivity) to operation
– Personality dominance
– Individual Prescriber Portrait
– Prescriber-centric SWOT
<b>Objective by prescriber (qualitative / quantitative)</b>
<b>Strategy and tactics by prescriber</b>
– Strategic priorities
– Individual Prescriber operational Mix
– Monitoring tools (KEIs <sup>1</sup> – KPIs <sup>2</sup> )

- The Individual Prescriber Plan is structured like a Brand Plan, but analyses are carried out from the prescriber's perspective
- The situation analysis section should highlight, for each prescriber:
  - The driving forces that influence his prescribing behavior
  - His preferred communication channels and the ones likely to influence him the most
  - His personality (relational, economic, scientific)
- The prescriber-centric SWOT should consider the prescriber's prescription potential, as well as his values, perceptions and motivations
- A qualitative and quantitative objective should be set prescriber by prescriber
- Strategy and tactics should aim at:
  - Creating more value for the prescriber
  - Reinforcing his preference for the brand
- KEIs<sup>1</sup> and KPIs<sup>2</sup> should be defined to ensure appropriate execution and resource allocation

**Before making the decision to invest in operations<sup>1</sup> at targeted prescribers, expected impact should be clearly defined, as well as execution and performance indicators**

### Tool

Check-list to support operational investment decisions

Illustrative

What is the objective of the action?	What are the KEIs <sup>2</sup> ?	What are the KPIs <sup>3</sup> ?
<ul style="list-style-type: none"> <li>▪ Create / reinforce awareness</li> <li>▪ Generate interest</li> <li>▪ Develop brand preference</li> <li>▪ Increase share of prescription</li> <li>▪ Increase compliance</li> <li>▪ Limit substitution rate</li> <li>▪ Get the brand listed</li> <li>▪ Fine tune the profile of the prescriber or of other customers</li> </ul>	<ul style="list-style-type: none"> <li>▪ % of the target covered by the action</li> <li>▪ % of the target exposed to the action</li> <li>▪ % of the target impacted by the action</li> <li>▪ % of the target having a positive opinion of the action (usefulness, Interest, practicality, quality of execution)</li> <li>▪ Implementation time required vs. planned</li> <li>▪ Actual vs. budgeted cost</li> </ul>	<ul style="list-style-type: none"> <li>▪ Brand Preference Mix index</li> <li>▪ Preference Ladder step</li> <li>▪ Key message memorization rate</li> <li>▪ Share of prescription</li> <li>▪ Sales evolution</li> <li>▪ Variation in the number of treatment initiations</li> <li>▪ Profit evolution in euros</li> <li>▪ % of hospitals having listed the brand</li> <li>▪ Return on investment</li> </ul>

Sources: "Pharma Marketing Tool box", J.-M. Peny, Smart Pharma Consulting, 2008, 213 p

<sup>1</sup> Medico-marketing-sales activities – <sup>2</sup> Key execution indicators – <sup>3</sup> Key performance indicators

The a priori and a posteriori assessment tools help objectivize that planned or existing activities will significantly contribute to reinforce the Brand Preference Mix

## Tool

### A priori assessment tool

Description	Objective	Target (HCPs, patients, etc.)
Expected Value by the Target		Exclusivity
Evaluation*	Rationale	Evaluation
Interest	1 2 3 4 5	Total
Usefulness	1 2 3 4 5	Partial
Convenience	1 2 3 4 5	None
Execution	1 2 3 4 5	
Total	1 2 3 4 5	

### A posteriori assessment tool

Barriers	Rationale	KPIs (Key performance indicators)	KEIs (Key execution indicators)	Decision
Technical	• Implementation			GO
Regulatory	• Compliance			No GO
Economic	• Estimated cost and return			

Description	Objective	Target (HCPs, patients)
Perceived value by the target		Exclusivity
Evaluation*	Rationale	Evaluation
Interest	1 2 3 4 5	Total
Usefulness	1 2 3 4 5	Partial
Convenience	1 2 3 4 5	None
Execution	1 2 3 4 5	
Total	1 2 3 4 5	

Link to the product		Evaluation**	Rationale
Magnitude	f – M - F		
Sustainability	f – M - F		

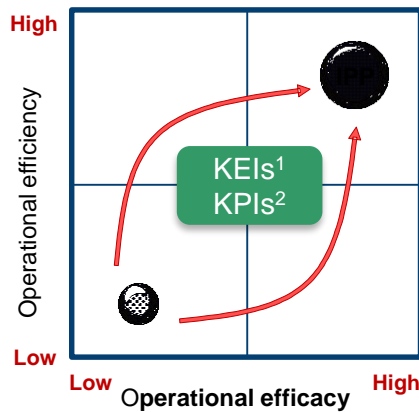
Impact on brand preference	Rationale	Solutions to reinforce toe preferential power	
		Initiatives	Evaluation
High		1	
Moderate	✓	2	
Low		3	
None		4	



# The Individual Prescriber Plan enables pharmaceutical companies to turn prescriber insight into competitive advantages in a more effective and efficient manner

## Benefits

### Operational Performance Matrix



#### Key Execution Indicators (KEIs¹)

- Level and mix of operational activities (medico-marketing-sales) vs. plan
- Quality of execution of activities:
  - Disease, competition and brand knowledge
  - Management of health economics issues
  - Ability to handle questions and objections
  - Knowledge and understanding of prescriber's profile
  - Adjustment of communication style and of message content to the prescriber's profile
  - Ability to trigger multi-channel initiatives
  - % of calls carried out with an iPad

#### Key Performance Indicators (KPIs²)

- Impact on performance:
  - Level of sales and evolution (in euros, units, prescriptions, patients)
  - Level of prescription share and evolution (in euros, units, prescriptions, patients)
  - Level of initiations and evolution
  - Level of prescription switches and evolution (of prescriptions, patients)
- Impact on behavior:
  - Level of prescriber interest
  - Product memorization rating
  - Intention to prescribe rating

- The Individual Prescriber Plan (IPP) is a useful tool to support a Prescriber-Centric Strategy
- Prescribers' experiences and perceived values with:
  - The brand
  - The services related to the brand
  - The pharmaceutical company
 are captured and analyzed with the help of the Brand Preference Mix Index (BPMI)
- The Behavioral Prescriber Segmentation (BPS) provides an accurate knowledge of each prescriber:
  - Prescription potential for the market and the brand
  - Permeability to operational<sup>3</sup> channels, messages and communication styles
- Thus, it is possible to design a fine-tuned “business plan” for each (key) prescriber, in such a way that operational efficacy and efficiency are optimized
- The quality of execution will be tracked with KEIs and the performance measured with KPIs

**The Individual Prescriber Plan<sup>1</sup> should be precisely elaborated by a team of collaborators interacting, on a regular basis, with the concerned prescribers**

### Method

#### Exploring Individual Prescriber insight<sup>2</sup>

- Key questions to be answered:
  - Who are the most critical prescribers to focus on to develop brand growth?
  - What will drive their brand preference?
- Ongoing exploration and discovery of individual prescriber insight are key to answering these two questions
- Prescriber-related insight collected by:
  - Medical representatives
  - Medical Scientific Liaisons (MSLs)
  - Other collaborators like Key Account Managers who meet prescribers or influencers
- Data should be stored in a shared database, opened to medical, marketing and sales collaborators that interact with prescribers<sup>3</sup>

#### Crafting Individual Prescriber strategy & tactics

- Prescriber insight must be translated into effective operational<sup>4</sup> activities likely to reinforce brand preference
- When there is a potential to create high reciprocal value for the prescriber and the company, a one-on-one customized program should be built according to the following steps:
  1. Evaluate the level of potential value for the prescriber and the company
  2. Understand individual prescriber needs, brand preferences, behaviors
  3. Create a “business plan” including services, communication styles, message contents and operational channels adjusted to each prescriber
  4. Track prescriber experiences and all aspects of his satisfaction to ensure high level of brand preference

#### Designing Individual Prescriber Plan<sup>2</sup>

- Each prescriber plan should be built by a “prescriber team” which includes the collaborators who interact with the prescriber and know him best
- The strategy and the corresponding tactics are supported by Individual Prescriber Portraits, which should be fine-tuned and updated by the team
- Before deciding to implement any operational activity, the following key questions should be answered:
  - What is the objective?
  - How should it be implemented?
  - What is the cost?
  - What is the expected impact?
- An individual action plan should be set

**The Brand Booster Program is a best-in-class program based on deep prescriber insight, value creation for prescribers and optimization of resource allocation**

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**Value of the Brand Booster Program (1/2)**

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- The **Brand Preference Mix** is the central pillar of the **Brand Booster Program** developed by Smart Pharma Consulting
- To create a strong and sustainable brand preference, marketers can identify the root causes of prescribers brand valuation with the help of the Brand Preference Mix Index
- The **Behavioral Prescriber Segmentation** approach makes it possible to get deeper insight regarding prescribers' needs, motivation, behavior and experience that are all essential to target the most attractive prescribers:
  - Those who have a high potential of prescription growth for the market<sup>1</sup> and the brand
  - Those who are the most permeable to medico-marketing-sales activities
- The **Individual Prescriber Plan** is a key element to help pharmaceutical companies express their strategic priorities and tactics in terms of value creation per prescriber and to align their resources accordingly to create a sustainable brand preference in an effective and efficient way

**The Brand Booster Program is a powerful and comprehensive approach, based on three components, enabling Marketers to optimize the performance of their brands**

### Value of the Brand Booster Program (2/2)

Brand Preference Mix	Behavioral Prescriber Segmentation	Individual Prescriber Plan
<ul style="list-style-type: none"> <li>By <b>measuring</b> the <b>performance</b> of their brand with the <b>BPM Index</b>, marketers will be able to:               <ul style="list-style-type: none"> <li>Define their <b>strategic priorities</b> to strengthen prescribers preference</li> <li>Evaluate the <b>impact</b> of their <b>strategies</b> and of the corresponding <b>tactics</b></li> </ul> </li> <li>The <b>BPM Index</b> should be calculated for <b>each</b> targeted <b>client once or twice a year</b></li> <li>Based on the analyzed results, a series of <b>customized actions</b> will be <b>defined</b> and <b>implemented</b> at <b>individual prescriber level</b></li> </ul>	<ul style="list-style-type: none"> <li>The BPS enables marketers to fine-tune operational<sup>1</sup> investments per prescriber...</li> <li>... by identifying:               <ul style="list-style-type: none"> <li>His capability/willingness to prescribe the competing brands</li> <li>The driving forces influencing his prescribing behavior</li> <li>His permeability<sup>2</sup> to operations</li> <li>Acceptable/convincing messages</li> <li>Appropriate style of communication</li> </ul> </li> <li>The BPS success requires:               <ul style="list-style-type: none"> <li>The <b>implementation of a simple and systematic process</b> to collect data</li> <li>The development of <b>operational tools</b> that take into account the <b>diversity of prescribers' behaviors and permeability</b></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>To make their brands preferred, marketers must develop:               <ul style="list-style-type: none"> <li>A <b>prescriber-centric strategy/tactics</b></li> <li>A <b>prescriber-centric brand plan</b></li> </ul> </li> <li><b>Prescriber-centric strategy</b> is about creating positive experiences through the three components of the BPM</li> <li>This requires deeper insight to develop strategies and tactics to intensify their positive perception</li> <li>A <b>prescriber-centric brand plan</b> captures the prescriber perspective and estimates his real perception of the company, its products and its services</li> </ul>

## Smart Pharma Consulting services related to Marketing include consulting support, organization of specific marketing training and regular publications

### Overview

Marketing Consulting	Marketing Training	Marketing Publishing
<ul style="list-style-type: none"> <li>Our consulting services range from presentations at seminars to implementation of conventional or innovative marketing strategies</li> <li>We help Marketers: <ul style="list-style-type: none"> <li>– Craft robust <b>brand strategies</b> and...</li> <li>– ... translate them into relevant <b>tactics</b></li> <li>– Ensure the appropriate <b>monitoring</b> of tactics with <b>KEIs<sup>1</sup></b> and <b>KPIs<sup>2</sup></b> to optimize the <b>resource allocation</b> (we have worked on more than 70 brands belonging to 16 therapeutic areas)</li> </ul> </li> <li>We also provide support with enhanced methodologies and tools to help optimize the management of product portfolio</li> </ul>	<ul style="list-style-type: none"> <li>Trainings are developed and carried out by our training center: <b>Smart Pharma Institute of Management</b></li> <li>Inter-company programs <ul style="list-style-type: none"> <li>– A comprehensive 5-day seminar: “<b>Pharma Strategy &amp; Marketing</b>”</li> <li>– 2-day <b>masterclasses</b>, of which three are specifically dedicated to marketing topics</li> </ul> </li> <li>Intra-company programs <ul style="list-style-type: none"> <li>– <b>Customized programs</b> to match the specific needs and expectations of marketing executives</li> <li>– In general 1- or 2-day programs</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Book <ul style="list-style-type: none"> <li>– <b>The Pharma Marketing Tool Box</b></li> </ul> </li> <li>Articles <ul style="list-style-type: none"> <li>– 30 published in specialized journals since 1993</li> </ul> </li> <li>Position papers <ul style="list-style-type: none"> <li>– 17 since 2010</li> </ul> </li> <li>Reports <ul style="list-style-type: none"> <li>– The French generics market (2015 – 2020)</li> <li>– Distribution &amp; économie de l'officine en France (2014 - 2020)</li> <li>– Global biosimilar drugs market outlooks</li> <li>– Le marché de l'automédication en France</li> <li>– Etc.</li> </ul> </li> </ul>

**As the author of the Brand Booster Program, Smart Pharma Consulting is the best positioned to ensure its smooth and efficient implementation by pharma companies**

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**Brand Booster Program Implementation**

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**Brand Preference Mix**

- Design and implementation of national studies to measure the Brand Preference Mix Index
- Design and facilitation of the implementation of Brand Preference Mix Index measurement at hospital/department and at prescriber levels through sales forces

**Behavioral Prescriber Segmentation**

- Presentation and training of the medico-marketing-sales departments to learn how to:
  - Collect prescriber insight to define an Individual Prescriber Portrait
  - Quantitatively and qualitatively adjust operational efforts for each targeted prescriber

**Individual Prescriber Plan**

- Design of a an Individual Prescriber Plan structure, including monitoring tools
- Training of marketers and other collaborators to correctly prepare Individual Prescriber Plans
- Challenge of teams involved in the preparation and development of Individual Prescriber Plans

## Smart Pharma Consulting supports national and international multi-disciplinary<sup>1</sup> brand teams with robust methodologies, practical tools and a challenging attitude

### Brand Teams Support & Challenge

#### Smart Pharma Experience & Approach

Support to 70 brands in 16 different disease areas:

- |                          |                           |
|--------------------------|---------------------------|
| 1. Addictology           | 9. Metabolism / Diabetes  |
| 2. Allergy               | 10. Neurology             |
| 3. Cardiology            | 11. Nephrology            |
| 4. Dermatology           | 12. Oncology / Hematology |
| 5. Gastroenterology      | 13. Ophthalmology         |
| 6. Gynecology            | 14. Pulmonology           |
| 7. Infectious diseases   | 15. Psychiatry            |
| 8. Metabolism / Diabetes | 16. Rheumatology          |

- We provide robust methodologies and practical tools to strengthen situation analyses
- We facilitate the identification of relevant strategic priorities to achieve pre-set objectives...
- ... and the selection of the corresponding tactics<sup>2</sup> including the appropriate monitoring tools<sup>3</sup>
- We positively challenge brand teams to enhance the quality of their analyses and recommendations

Key issues addressed by our approach

1. How to best evaluate the market dynamics and the brand performance?
2. How to measure the impact of recent investment decisions?
3. How to build market scenarios?
4. How to carry out an *Advanced SWOT*<sup>4</sup> analysis?
5. How to set rational performance objectives<sup>5</sup>?
6. How to define the corresponding relevant strategy with the help of the *Advanced SWOT* analysis?
7. How to determine the optimal mix and level of medico-marketing and sales investment per brand and across different brands of a portfolio?

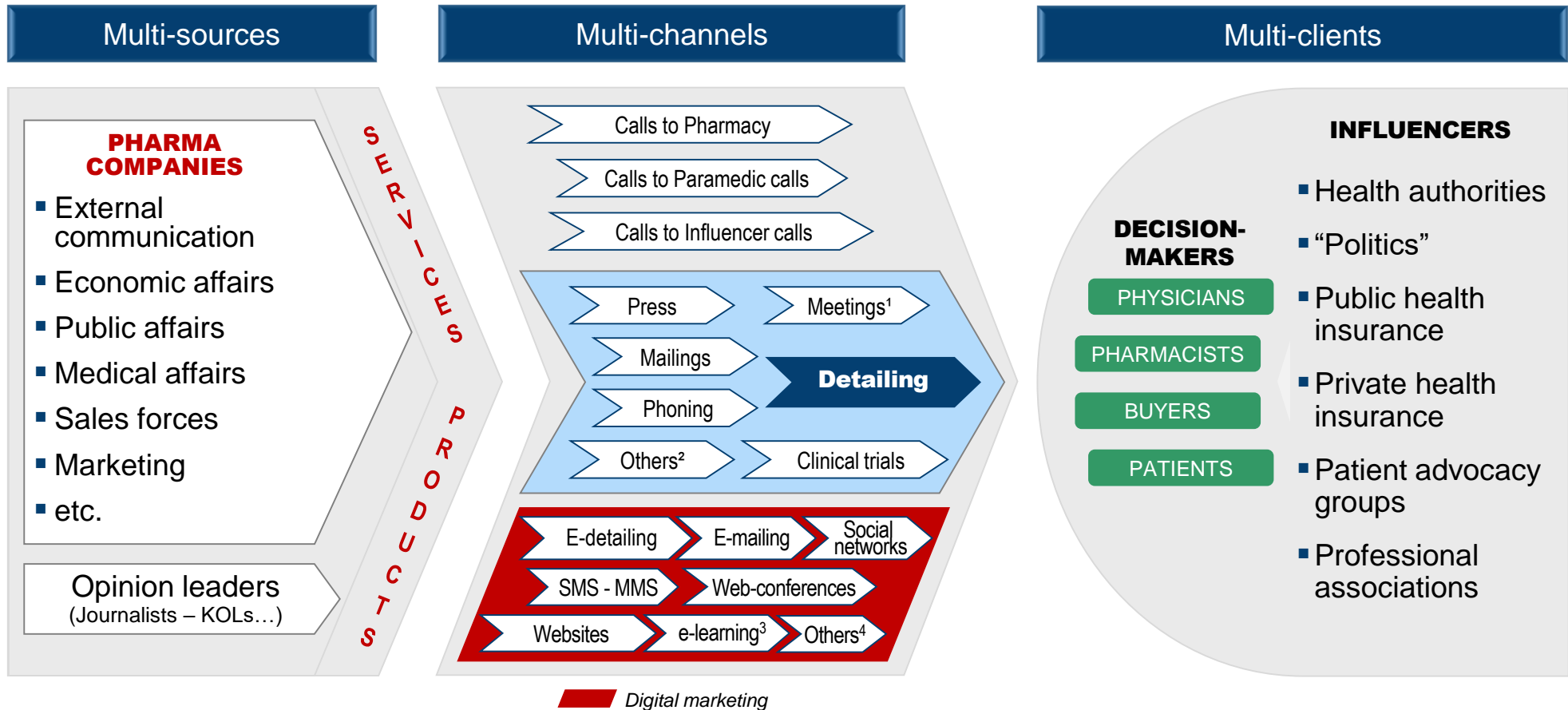






As prescription decisions increasingly depend upon multiple clients, pharma companies need to adopt a more complex and coordinated promotional approach

**New pharma marketing & sales model (1/2)**



Sources: Smart Pharma Consulting

<sup>1</sup> Round tables, symposiums, congresses, etc. – <sup>2</sup> Sampling, gimmicks, grants, prescription pads... – <sup>3</sup> Continuous medical education through a digital interface – <sup>4</sup> Screen savers, popup windows...

**Prescribers should be offered exceptional experiences during interactions with med reps to ease access and increase the preference to the brands they promote**

**New pharma marketing & sales model (2/2)**

- Lower number of breakthrough innovative products with high sales potential
- Increasing price pressure and narrowing of the target patient population by payers

- Tighter control of marketing activities (incl. medical calls) by authorities
- Higher proportion of physicians refusing to be called upon
- Portfolio evolution from primary to secondary care products
- Increasing role of other stakeholders<sup>1</sup> influencing physician prescriptions



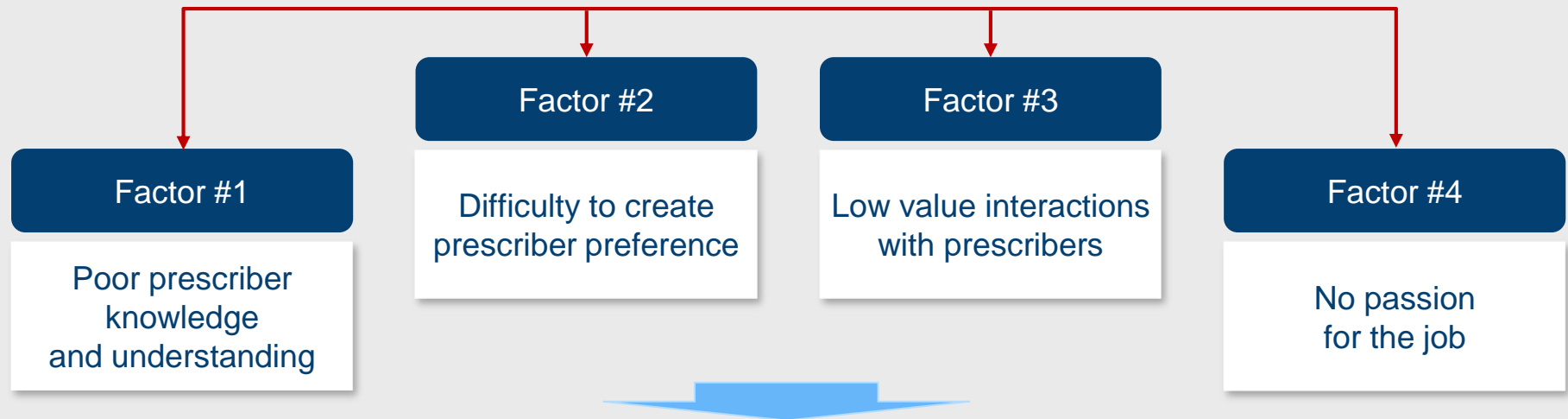
- Redefine the level of marketing and sales investments
- Switch priority from efficacy to efficiency (better return on investment)
- Adapt communication...
  - ... content to regulatory constraints
  - ... channels to other stakeholders<sup>1</sup>

- Development of CRM<sup>2</sup> and CLM<sup>3</sup> tools enabling a more precise profiling of physicians

Smart Pharma Consulting has identified four main reasons explaining the limited impact of med reps on the opinion and behavior of the prescribers they interact with

### Med reps performance limiters

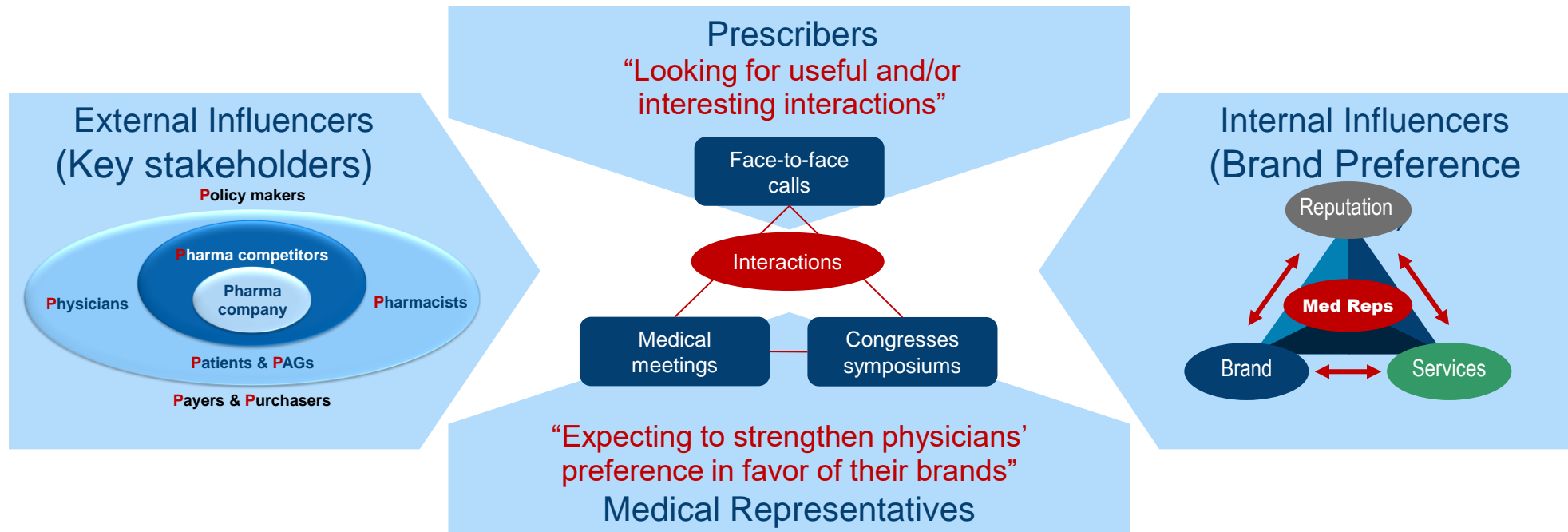
- Smart Pharma Consulting has identified **four main factors** responsible for **med reps underperformance**:



- To remove these limiting factors, we have recently developed the **ELITE Program** which helps med reps **reinforce the preference of prescribers for the brands they promote**

The ELITE Program can help med reps create interactions that are better valued by their customers and thus contribute to strengthen the preference for their promoted brands

### Objective of the ELITE Program



The ELITE Program assumes that prescribers opinion and corresponding prescribing behavior depend on:

- **External influencers** (key stakeholders)
- **Internal influencers** (Brand Preference Mix)
- **Their willingness to interact with med reps**
- **Med reps ability to create highly valued interactions**

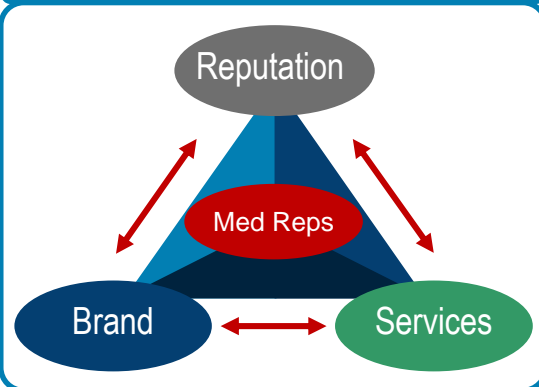
The ELITE Program is based on 4 pillars enabling med reps to interact more efficiently with prescribers and to optimize the prescription share of the brands they promote

**The Four Pillars of the ELITE Program**

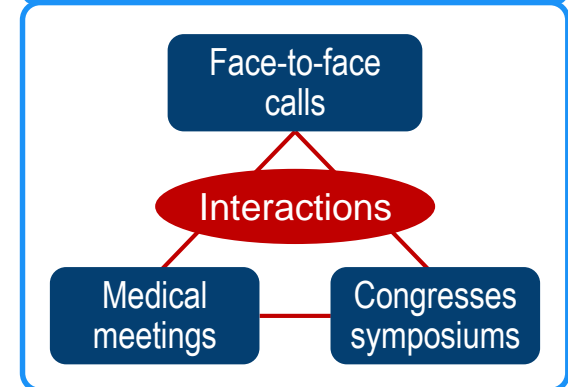
**1. Prescriber Insight**

Better Knowledge  
&  
Better Understanding **TO** Better Convince

**2. Brand Preference Tactic**



**3. High Impact Interactions**



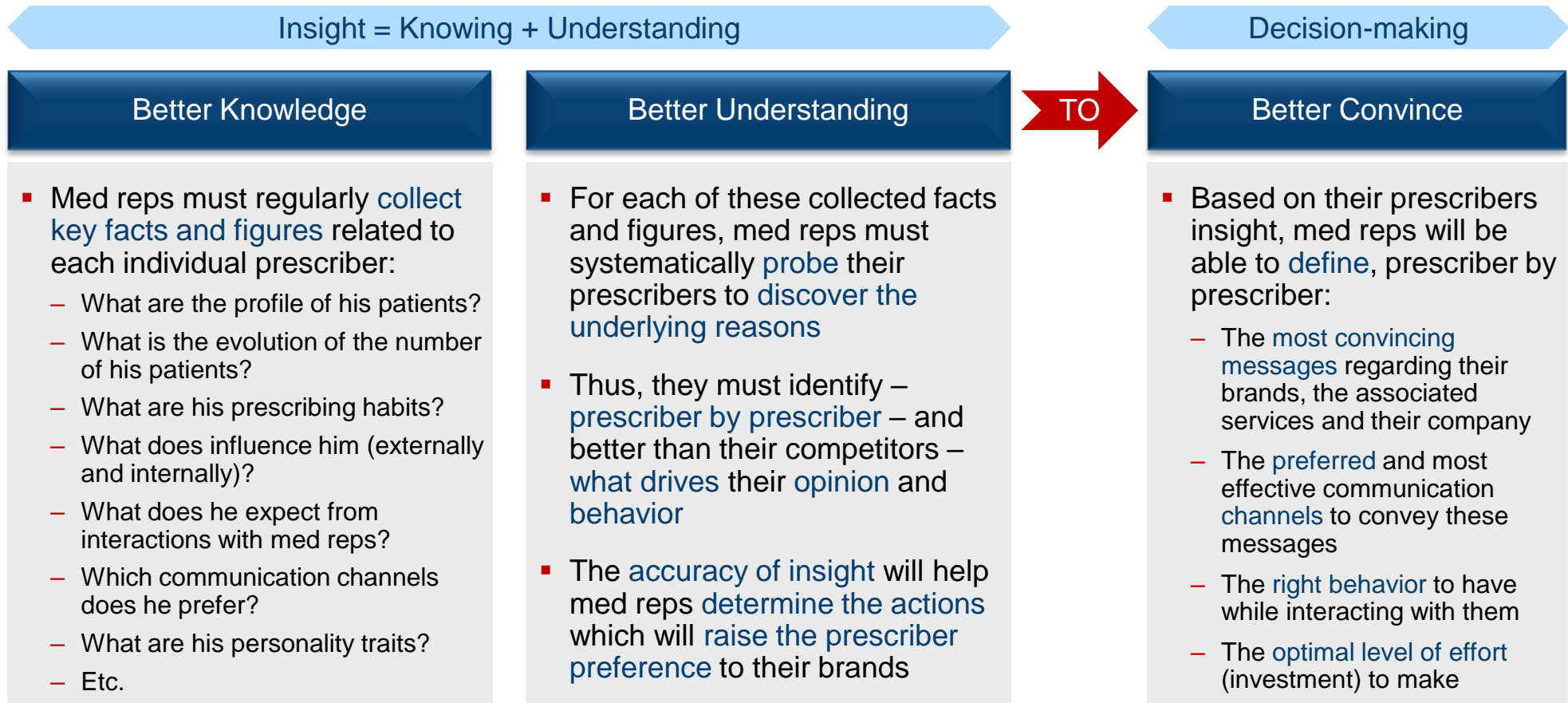
**4. Job Passion**

Job Passion **→** More & Better Work **→** Higher Performance



The in-depth knowledge and understanding of individual customer opinion and behavior are essential to set the optimal mix and level of activities to be devoted to each of them

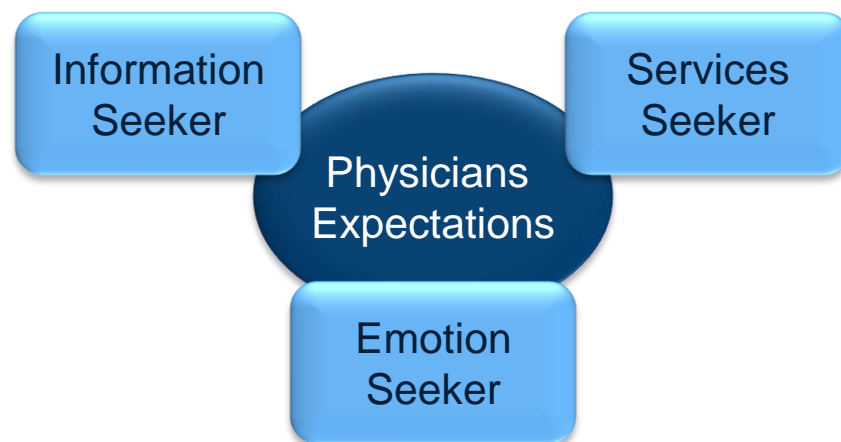
### How to build In-depth Prescriber Insight?



**While interacting with med reps, physicians look for: information, services, and/or emotion, knowing that one of these expectations is generally predominant**

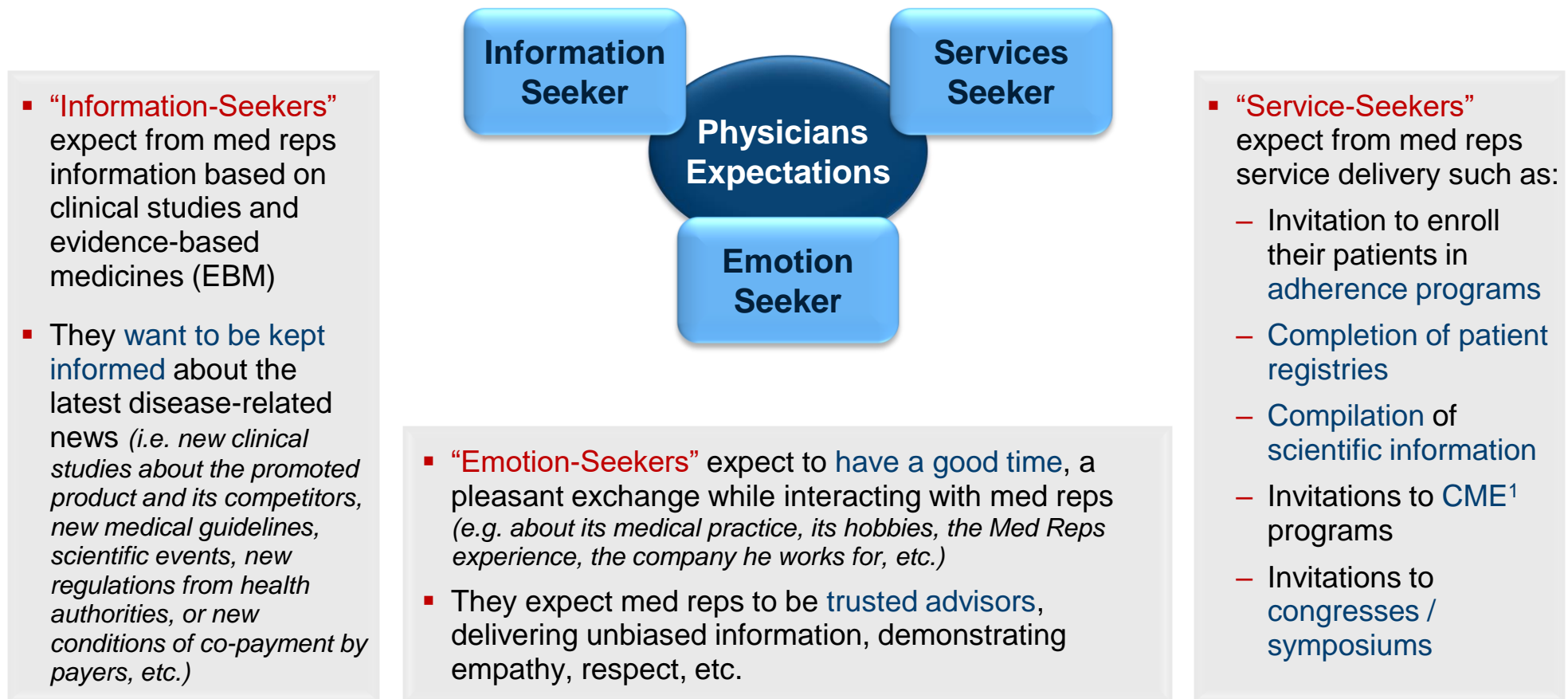
**The “Seeker Portrait” Model – Principle**

- Physicians expectations vis-a-vis med reps depend on:
  - External influencers<sup>1</sup>
  - Internal influencers (i.e. the history of their interactions with med reps and other collaborators<sup>2</sup> of their company)
  - Their personality
- The “Seeker Portrait” model can help med reps characterize what physicians will predominantly expect while interacting with them: **Information – Services – Emotion**
- If physicians expectations are in fact a mix of these three types, one will be dominant, reflecting their personality, their influences and their specific needs at a point of time
- Physician dominant expectations may vary:
  - Over time
  - With the brand status (innovative or me-too, new or established)
  - With med reps (according to their past interactions)



**To increase the probability of influencing favorably the opinion and behavior of each physician, med reps must define their dominant type of expectations**

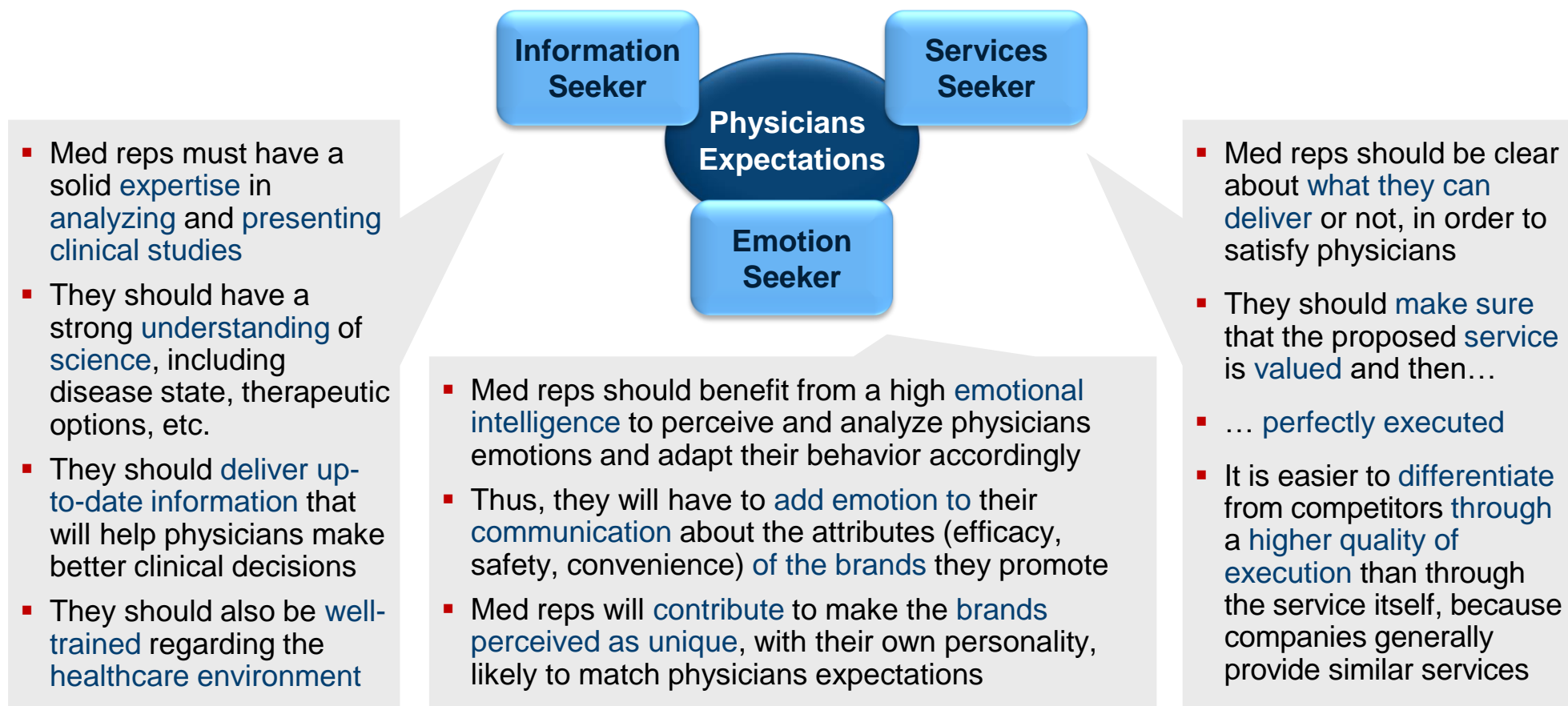
**The “Seeker Portrait” Model – Features**





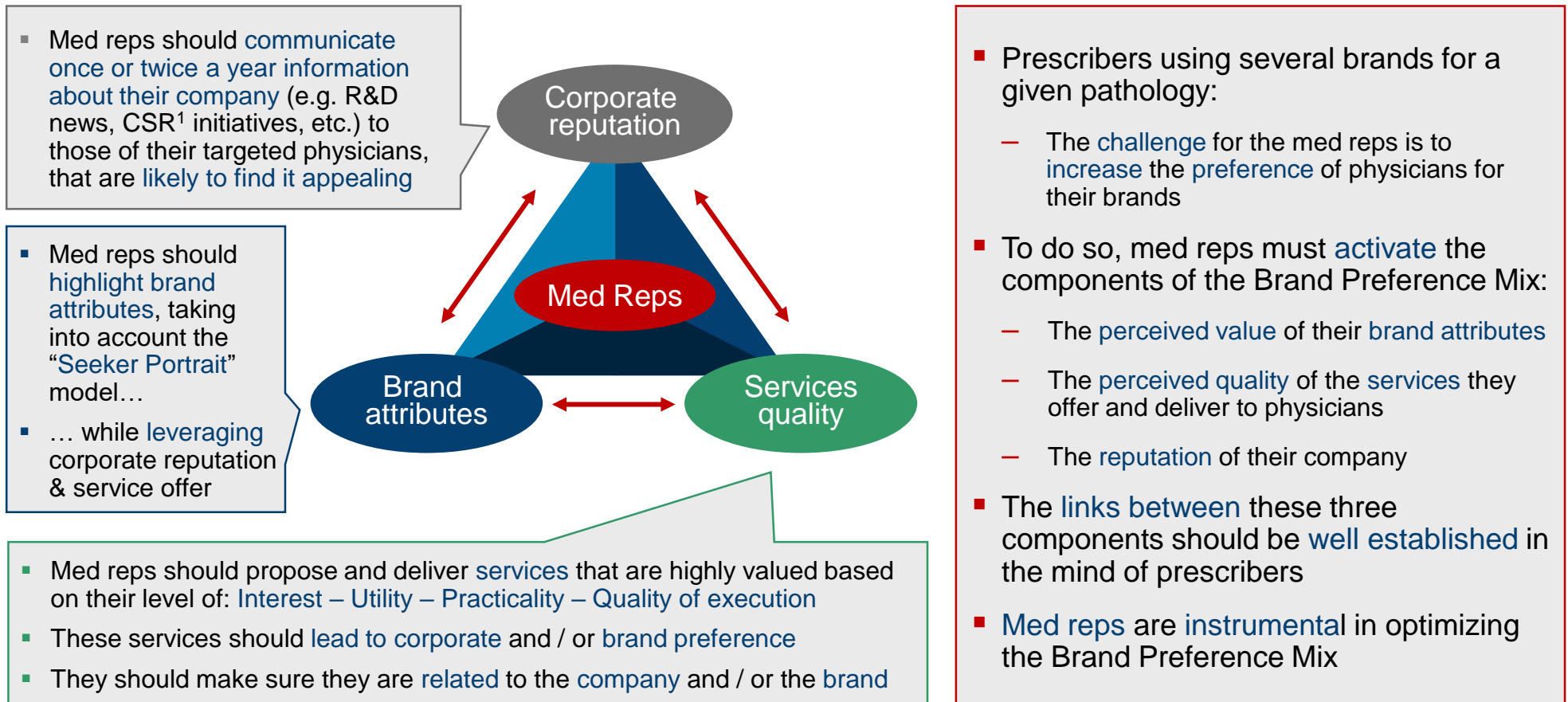
The different types of dominant expectations require from med reps different sets of skills and an adjustment of their behavior while interacting with physicians

**The “Seeker Portrait” Model – Implications for med reps**



## The Brand Preference Mix determines the key drivers that can be activated by the med reps to enhance the preference of their targeted physicians

### The Brand Preference Mix (BPM) – Principle

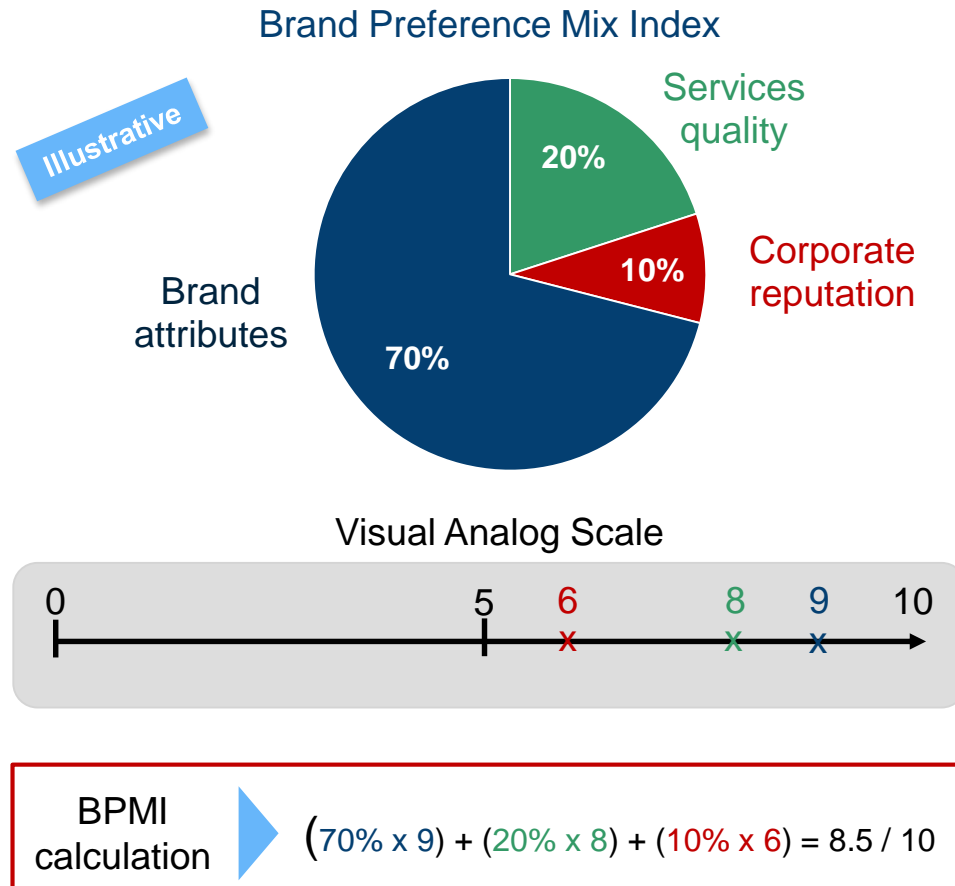


Sources: “Building prescriber loyalty”, J.-M. Peny et al., SCRIP Magazine, September 1993 – Smart Pharma Consulting

<sup>1</sup> Corporate social responsibility

The Brand Preference Mix Index (BPMI) enables to evaluate the brand performance on each of its preference components, over time and compared to its competitors

**The Brand Preference Mix (BPM) – Tool #1**



- The Brand Preference Mix Index (BPMI) is a measurement tool that takes into account:
  - The relative importance of each BPM component (i.e. corporate reputation, brand attributes and associated service quality) per brand
  - The score of the brand, on a 10-point scale, for each of its preference components
- The BPMI can be defined per customer<sup>1</sup>, per indication, per form, etc.
- The BPMI scores the customer perception at a given point in time, making possible to track the evolution of this perception over time and to compare it to competitors, considering:
  - External events (i.e. related to health authorities, competitors and customers' behaviors)
  - Internal events (i.e. related to operational activities<sup>2</sup>, quality of services offered, communication strategy)

Sources: "Building prescriber loyalty", J.-M. Peny et al., SCRIP Magazine, September 1993 – Smart Pharma Consulting

<sup>1</sup> Physicians, patients, pharmacists, nurses, payers, health authorities, etc.  
<sup>2</sup> Medico-marketing-sales

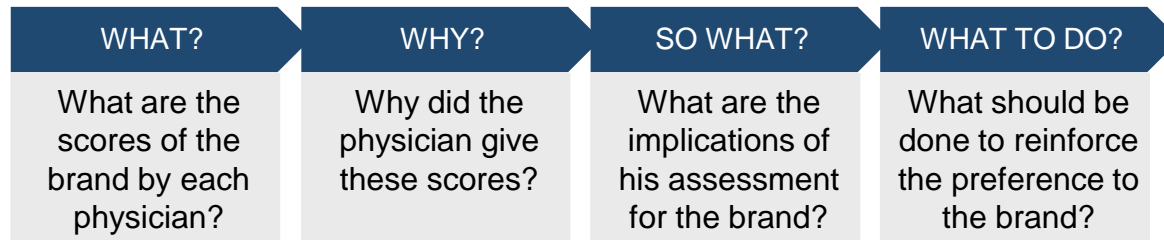
Med reps can monitor the brand performance with the “Brand Preference Mix Index” while calling upon their targeted physicians and thus, fine-tune their activities

**The Brand Preference Mix (BPM) – Tool #2**

Assessment guide for medical reps

The form is titled 'PROGRAMME D'AMELIORATION DE LA QUALITE' and is divided into several sections for medical reps to complete. It includes rating scales for product quality, associated services, and the laboratory's image, as well as open-ended questions for recommendations.

From observation to decision: The 4 Ws approach

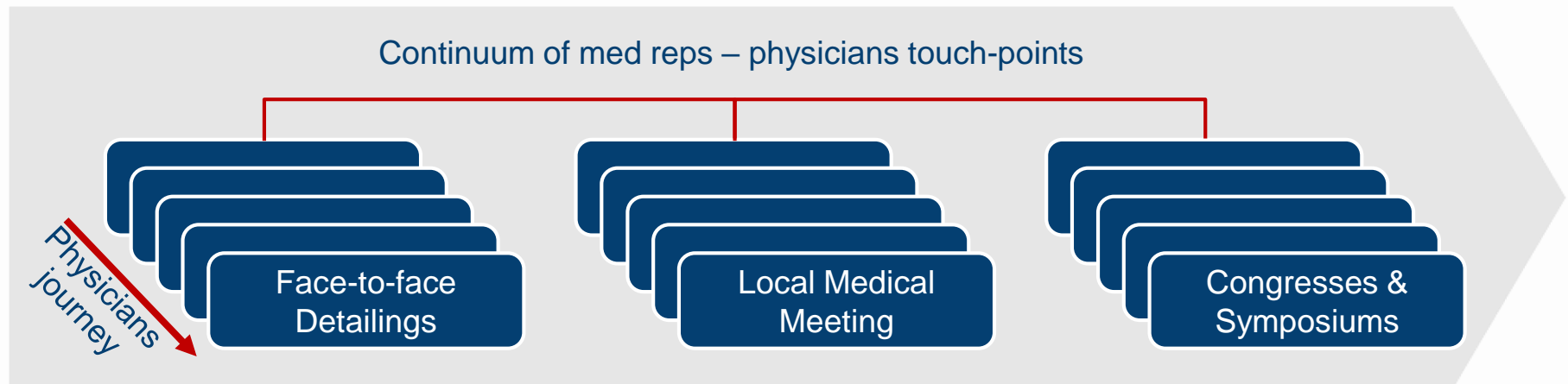


- Recent experiences have shown that:
  - >95% of physicians **accept to be questioned** on the three components of the BPM
  - >80% of physicians consider that the **BPM** approach **conveys a positive image**
  - >85% of medical reps say that the BPM **helps improve** their **insight** into physicians
- Once physicians have evaluated the brand with the BPM, they are asked:
  - What is the **rationale** supporting these **scores**?
  - What **should be done** to raise their preference to the brand?
- Then, **med reps** can **fine-tune** their **messages**, their **activities**, **physician by physician**, based on the feedback
- The collected **information** should be **shared** with **marketers** who will define specific initiatives to reinforce prescribers' preference to the brand

By offering physicians exceptional experiences while interacting with them, med reps access will be eased and the preference to the brands they promote increased

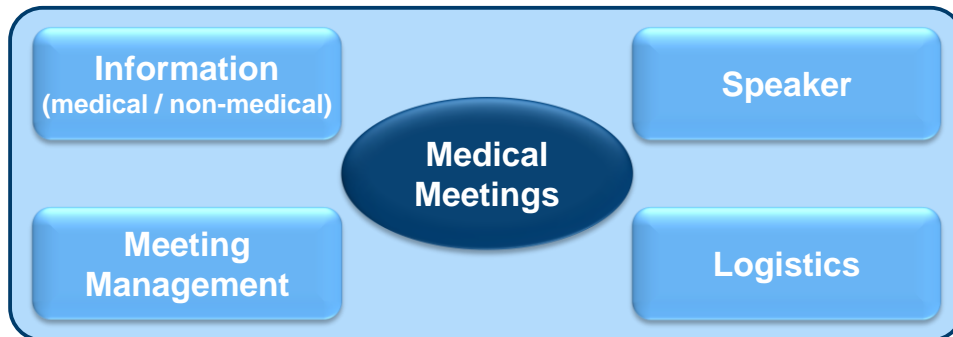
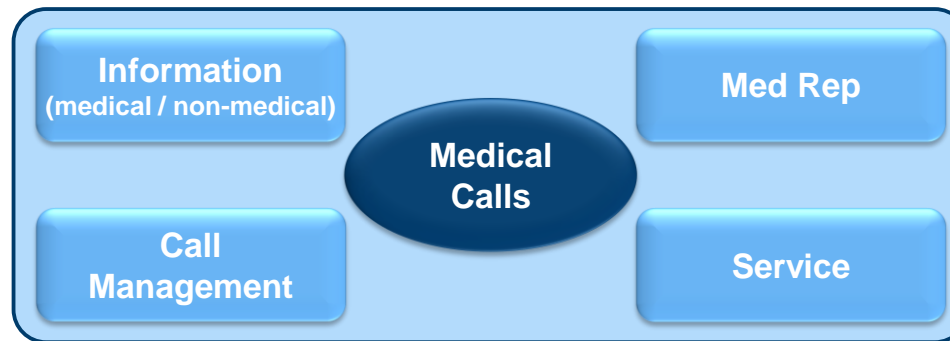
### Why to create High Impact Interactions?

- Smart Pharma Consulting has developed the “H2I Program” (High Impact Interactions Program) to help med reps<sup>1</sup> create a continuum of exceptional interactions with physicians so that they:
  - Accept (or even ask for) more regular contacts with med reps
  - Increase their preference for the brands promoted by the med reps



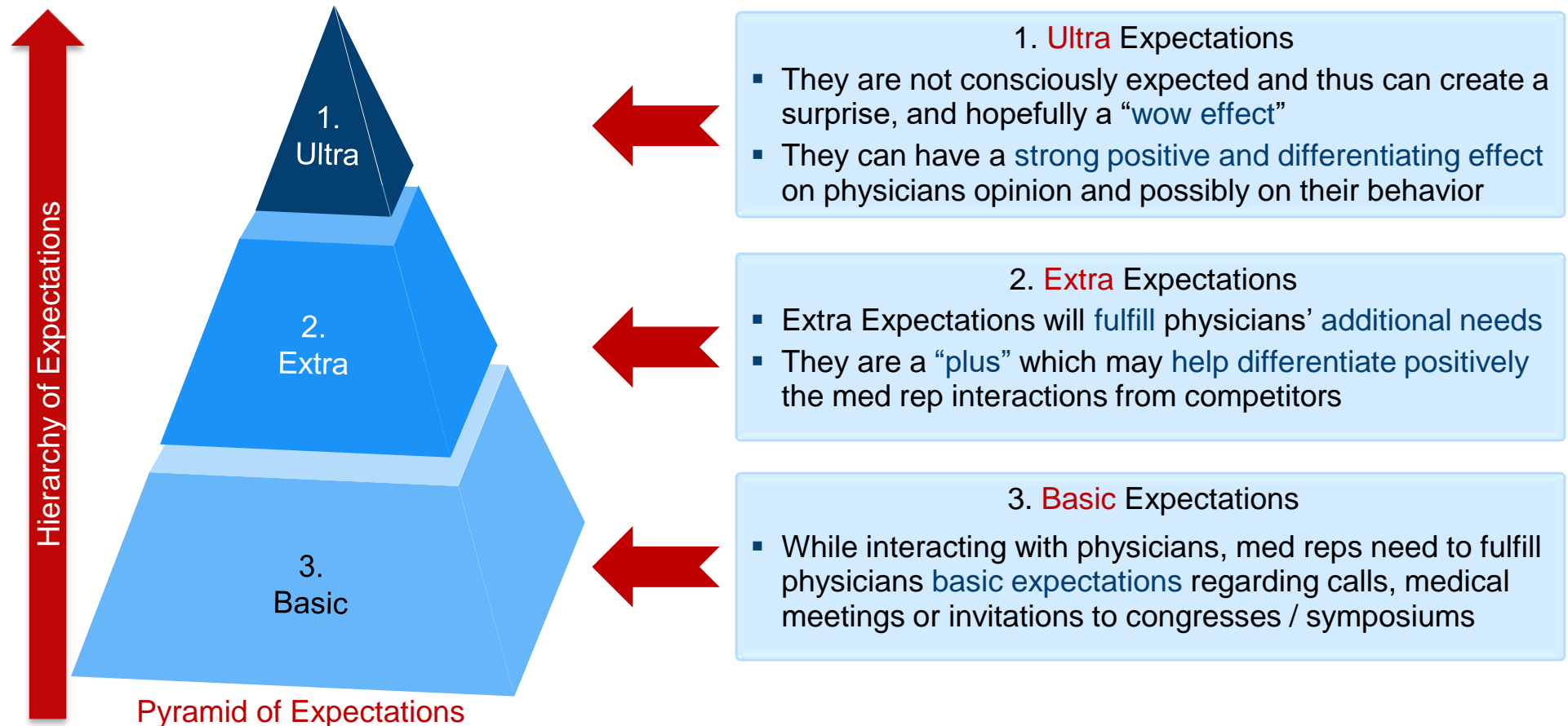
Physicians experience while interacting with med reps will depend on their assessment of the four determinants of the three following types of interactions

**High Impact Factors Identification**



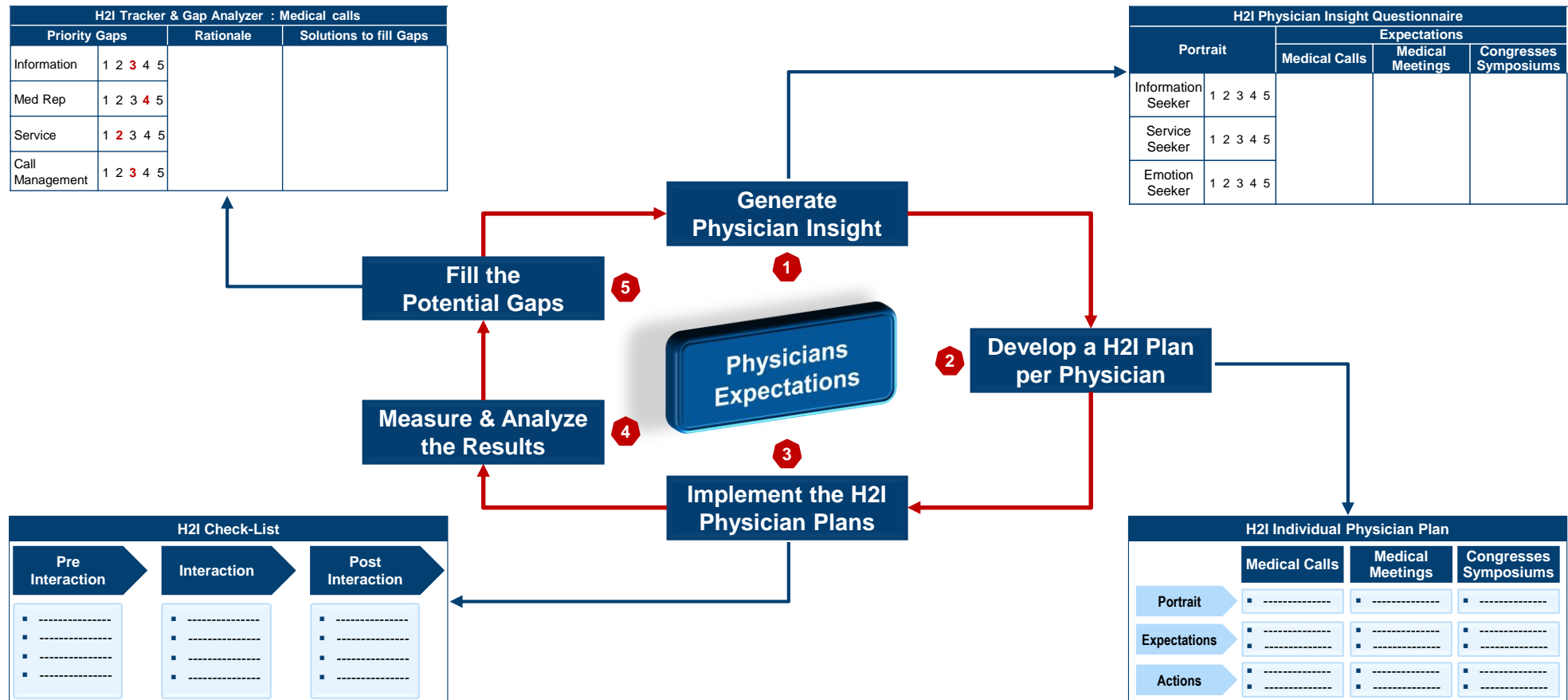
To create High Impact Interactions, med reps need to move up the pyramid of expectations in an attempt to offer physicians a continuum of unique experiences

**High Impact Interactions (H2I) Program – Principles**



For each of the five steps of the H2I Program, enabling tools will be designed to facilitate their proper execution by med reps

## High Impact Interactions (H2I) Program – Framework & Tools





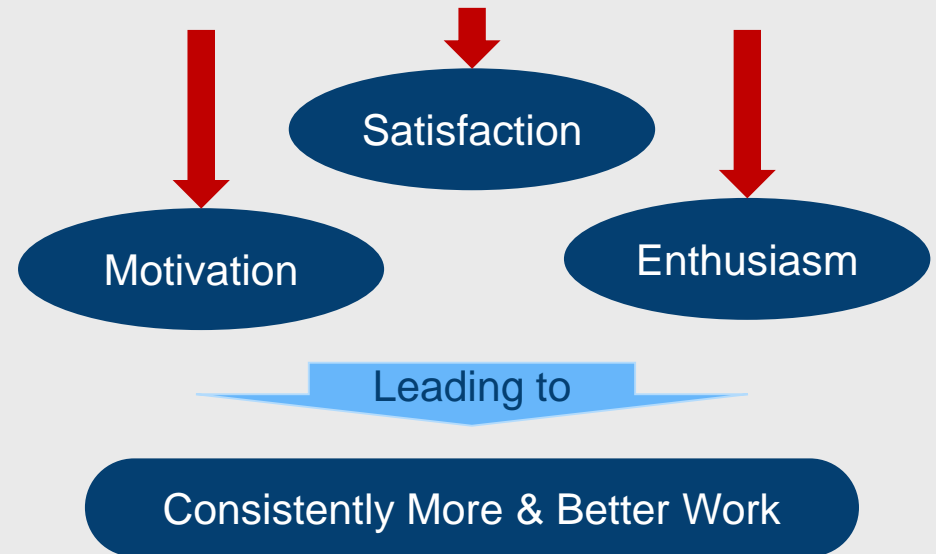
**Job passion lies on six key drivers that pharma companies may manage carefully if they want their med reps to give their best to achieve their objectives**

**What is Job Passion?**

- Job passion is influenced by **six key drivers**:



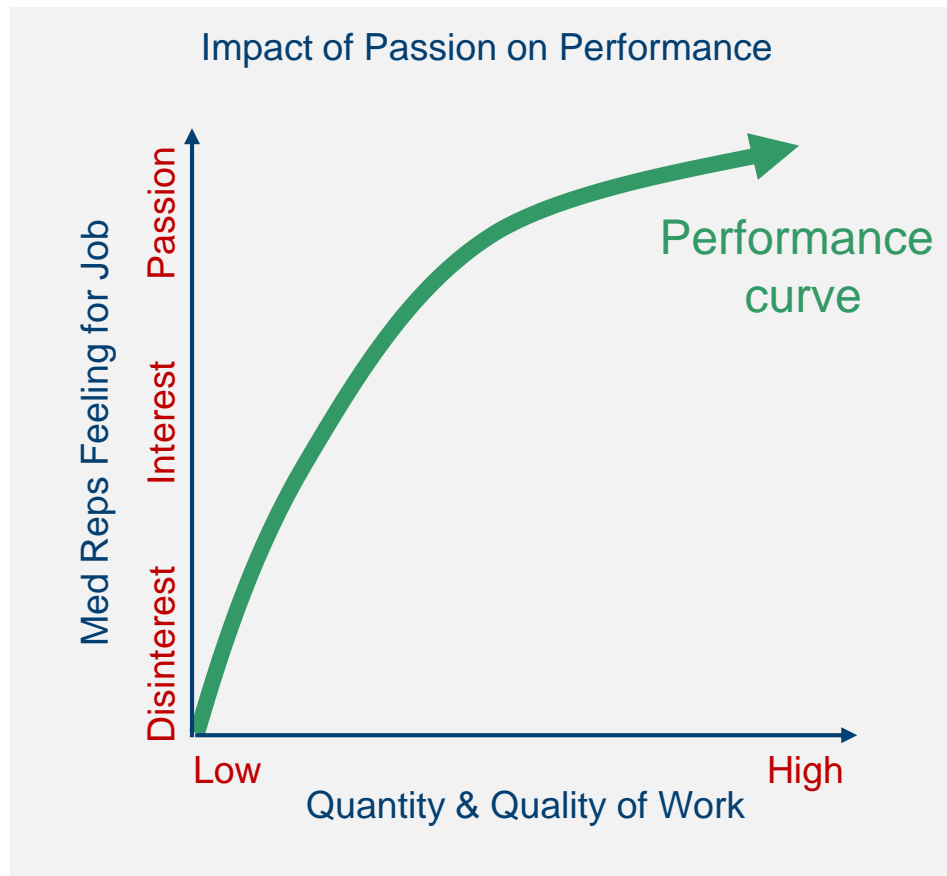
- Passion for a job is a **strong inner emotion** which is expressed by:



*"Passion is the difference between having a job or having a career"*

**As passionate med reps deliver better results than those who are not, pharma companies must recruit them, sustain their feeling and secure their loyalty**

**Why to stimulate Job Passion?**

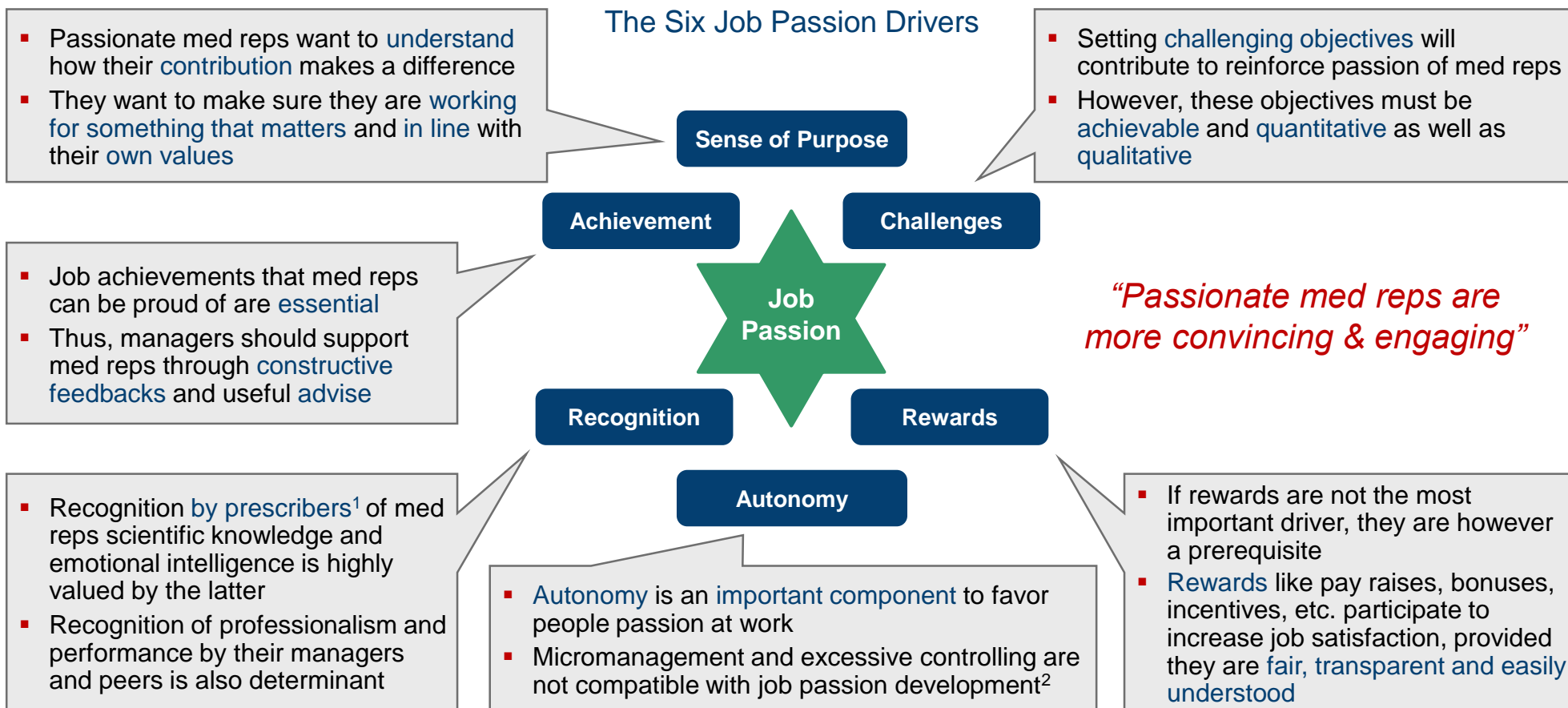


- Passionate employees<sup>1</sup> being more satisfied with their job and more motivated, they will tend to work longer hours and to work better
- Therefore, it is of the utmost importance for pharma companies to:
  - Recruit med reps that are passionate for their job
  - Create the working conditions to keep their passion up
  - Put in place a plan to retain them

*“Pleasure in the job  
puts perfection in the work” – Aristotle*

Pharma companies and especially area managers should keep up or even stimulate the passion of their med reps at work with the help of the six following drivers

### How to stimulate Job Passion?



**The best performing companies are able to develop deeper physicians insight and to create sustainable physicians experiences that stimulate their desire and preference**

---

**Key Success Factors (1/2)**

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**Develop  
Insight**

- Interactions should be used to better know and understand physicians needs...
- ... and to identify what is likely to please, impress, delight, or positively surprise them

**Instill a  
Culture**

- The ELITE Program should come from the top management and disseminate throughout the company to reach med reps who need to understand the benefits they will draw from such a program

**Define a  
Strategy**

- The ELITE Program should be part of a broader strategy aiming at strengthening physicians preference to the promoted brands
- Thus, it should be integrated into the brand marketing and sales strategy

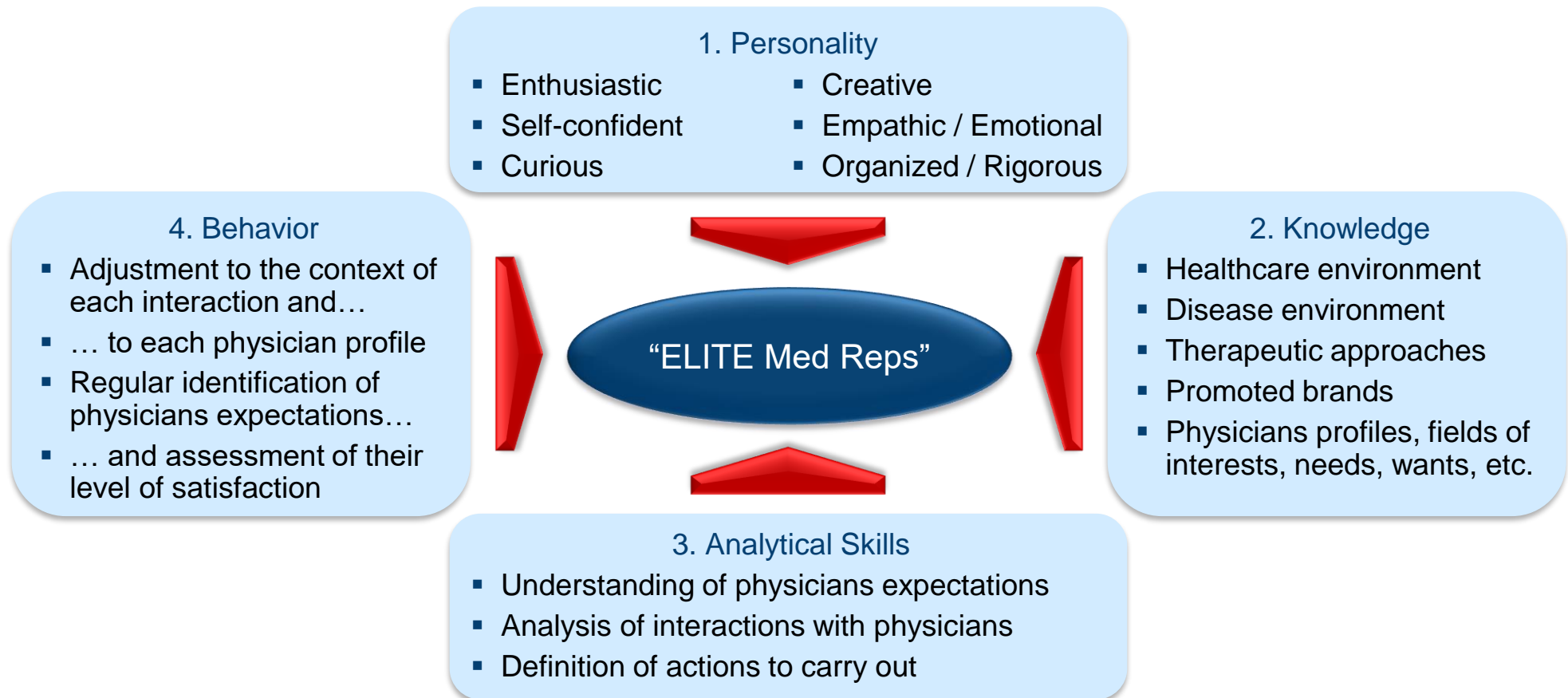
**Design a Process**

- The ELITE Program should be implemented, according to a well-defined process, to ensure a consistently high quality of execution...
- ... and monitored with specific metrics to fill the gaps, if any, with proper solutions

*“Excellence is doing ordinary things extraordinarily well” – John W Gardner*

To obtain quick and tangible results, “ELITE Med Reps” would need to adjust their behavior, certain traits of their personality and improve their technical skills

**Key Success Factors (2/2)**



## Smart Pharma Consulting services related to med reps performance include consulting support, organization of specific trainings and regular publications

### Overview

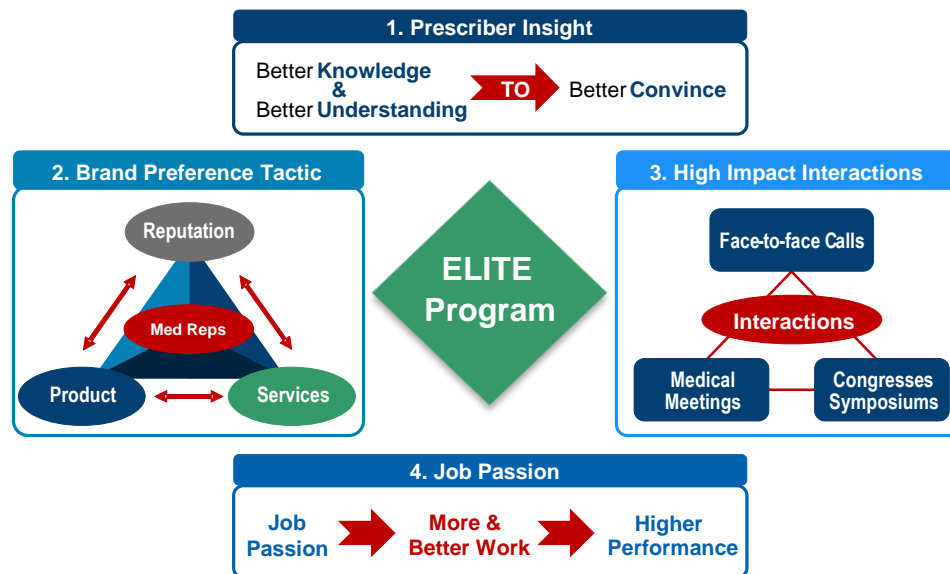
Consulting	Training	Publishing
<ul style="list-style-type: none"><li>■ Our consulting services related to med reps <b>range from lectures</b> at seminars <b>to implementation of innovative methods</b> such as the ELITE or the STAR<sup>1</sup> programs</li><li>■ Thus, we help pharma companies improve:<ul style="list-style-type: none"><li>– Their customer targeting (see “Best-in-Class Pharma Marketing”<sup>2</sup>)</li><li>– The organization of their sales forces (sizing, territorialization, activity prioritization and planning at national, area, territory levels, etc.)</li><li>– The management of their med reps (motivation, development of collaborators) by their managers</li></ul></li></ul>	<ul style="list-style-type: none"><li>■ Trainings are developed and carried out by our training center: <b>Smart Pharma Institute of Management</b></li><li>■ Inter-company programs<ul style="list-style-type: none"><li>– A comprehensive 5-day seminar: “Pharma Strategy &amp; Marketing”<sup>3</sup></li><li>– Four <b>Masterclasses</b>, of one or two days dedicated to med reps</li></ul></li><li>■ Intra-company programs<ul style="list-style-type: none"><li>– <b>Customized programs</b> to match the specific needs of pharma companies regarding their sales force</li><li>– In general one- or two-day programs</li></ul></li></ul>	<ul style="list-style-type: none"><li>■ Books<ul style="list-style-type: none"><li>– The “<b>Pharma Marketing Tool Box</b>” (2 editions: 2008 and 2015)</li><li>– <b>Pharma Market Insight &amp; Strategy</b> (4 books analyzing the future of the global pharma market and the implications for pharma companies)</li></ul></li><li>■ Articles<ul style="list-style-type: none"><li>– 42 published in specialized journals</li></ul></li><li>■ Position papers<ul style="list-style-type: none"><li>– 50 since 2012 (e.g. organizational benchmarking of in-field collaborators, brand preference mix, creation of high impact interactions, etc.)</li></ul></li><li>■ Reports<ul style="list-style-type: none"><li>– 15 since 2012 (e.g. generics, OTCs, biosimilar markets, digital marketing, distribution and retail pharmacies economic trends, market access, etc.)</li></ul></li></ul>

**As the author of the ELITE Program and considering their operational experience, Smart Pharma consultants are well positioned to facilitate its implementation**

### ELITE Program Implementation

- Smart Pharma Consulting has an **in-depth expertise** in improving sales force efficiency coming from:
  - **General management experiences** in France and abroad for pharma companies
  - **Numerous** sales force effectiveness consulting **projects** carried out since 2001 (e.g. 4 in 2016)
- The ELITE Program which has been developed by Smart Pharma Consulting proposes an **holistic** and **practical** approach to **obtain** a significant **improvement** of **med reps efficiency** and **efficacy**
- Smart Pharma Consulting can help pharma companies implement the ELITE Program as follows:

1. Craft a communication strategy demonstrating to med reps the benefits they will draw from the program
2. Design a framework that fits the company ambition and takes into account its current situation
3. Create specific and user-friendly tools to facilitate the execution of the four pillars of the ELITE Program by the med reps

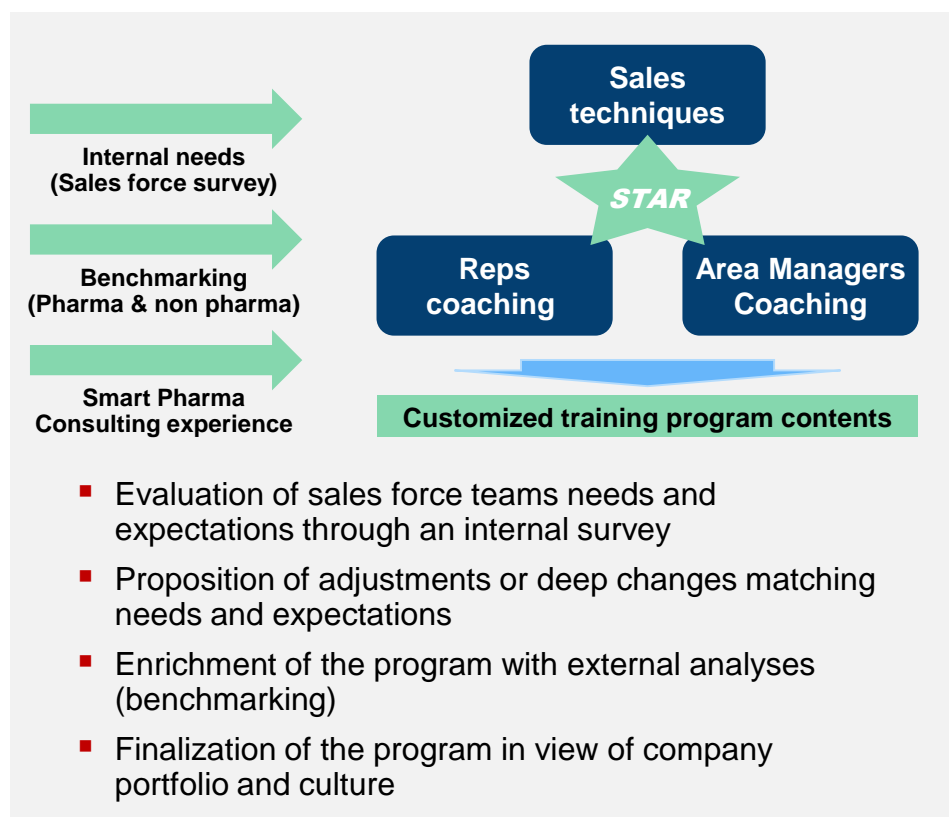


4. Develop specific training modules<sup>1</sup> for med reps and their managers to help them master:
  - The concepts
  - The methods
  - The tools
 related to each of the four pillars that constitute the ELITE Program
5. Adjust the organization to best support the execution of the ELITE Program

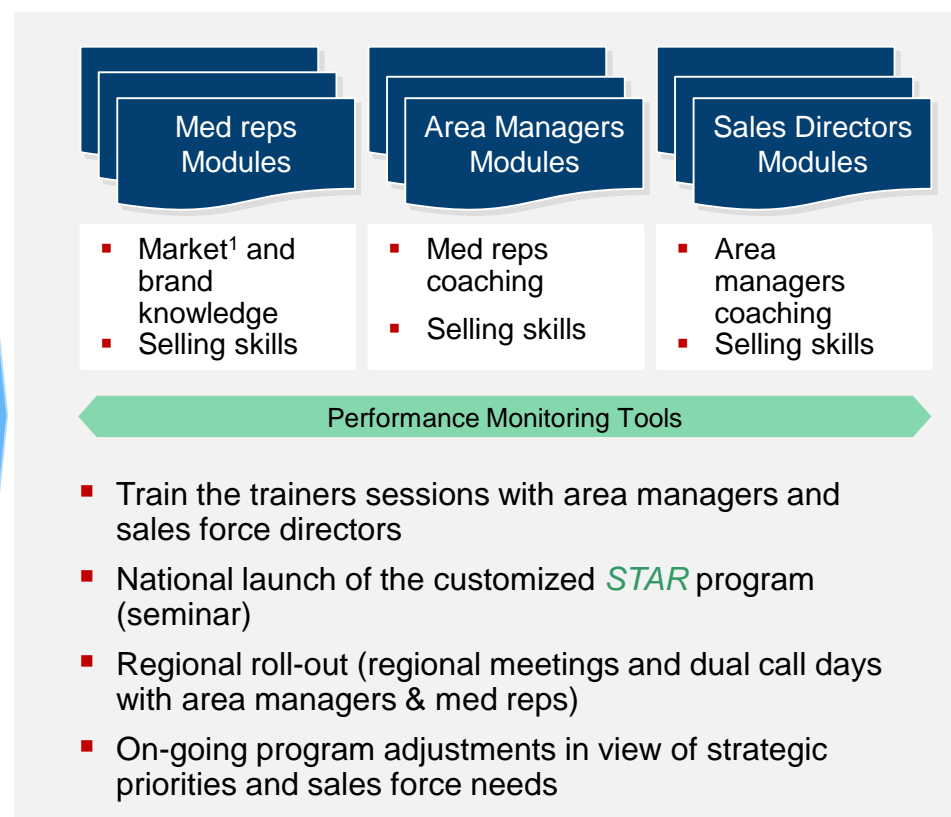
The STAR (Sales Techniques Application for Results) program can be entirely customized to pharma companies needs and rolled out in a timely manner

## STAR Program Implementation

### Identification of sales force needs and expectations



### Program roll-out



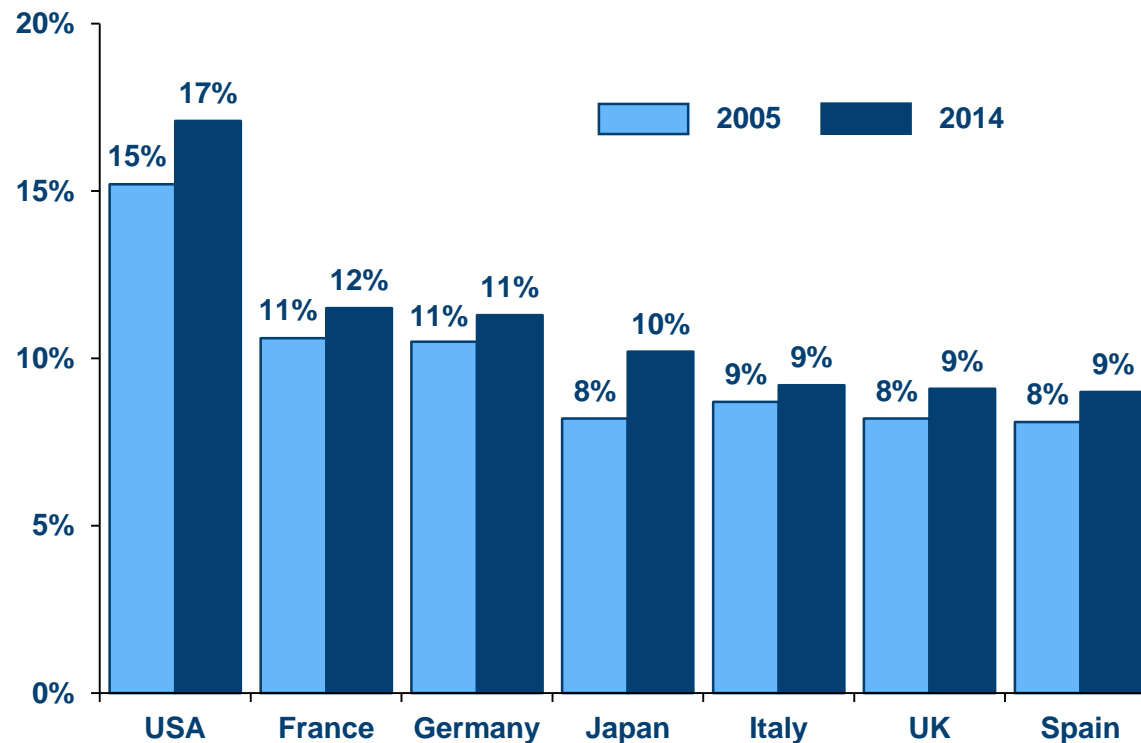




## Healthcare expenditure will keep on growing faster than national economies due to demographic factors and willingness of citizens to have better access to healthcare

### Healthcare expenditure as a percentage of GDP<sup>1</sup>

Total healthcare expenditure as a % of GDP<sup>1</sup>  
(Local currency)



- Healthcare expenditure represented one of the largest public spending items in most developed economies: 1<sup>st</sup> (USA), 2<sup>nd</sup> (France, Germany, Japan and UK)<sup>2</sup> and 3<sup>rd</sup> (Italy and Spain)<sup>3</sup>
- 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
- There is no optimal ratio of healthcare expenditure to GDP, it primarily results from:
  - Public health conditions
  - Governments investment prioritization
  - Citizens willingness to seek for care
  - Healthcare cost

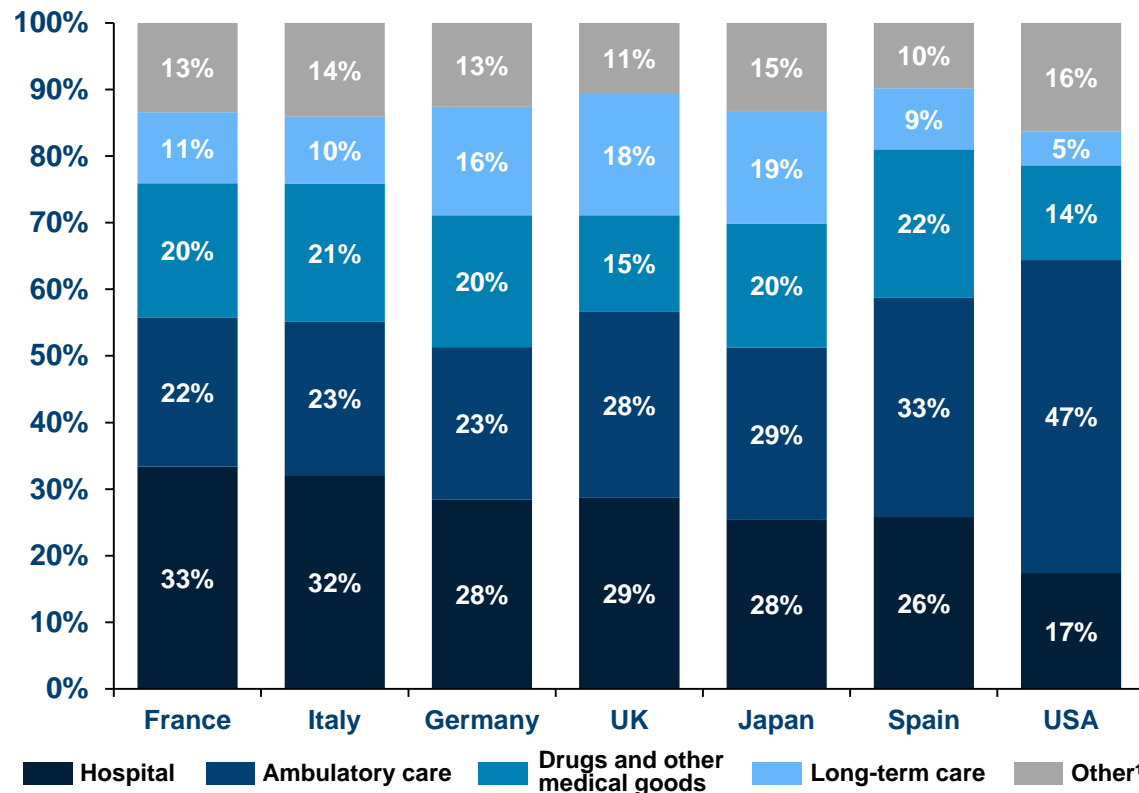
Sources: World Bank, as of September 2017 – OECD, as of September 2011<sup>17</sup>

<sup>1</sup> Gross Domestic Product – <sup>2</sup> After social protection – <sup>3</sup> After social protection and general public services  
\* Note: 2014 data excepted for France and the USA, 2015

The cost of drugs is far behind that of hospital and ambulatory care, yet this segment is paradoxically targeted by governments because it is easier and quicker to reduce

### Breakdown of healthcare expenditure per country (2015)

% of total healthcare expenditure



- Drugs represent the 3<sup>rd</sup> largest source of healthcare expenditure in major developed countries
- Drugs are typically the easiest segment to apply cost-containment measures on, as decisions are:
  - Made by payers (either public and/or private), with a limited bargaining power of suppliers
  - Much better accepted by citizens than restriction measures on the other segments
- However, to significantly reduce total healthcare costs, governments will need to apply cost-optimization measures on all healthcare segments, irrespective of their relative importance

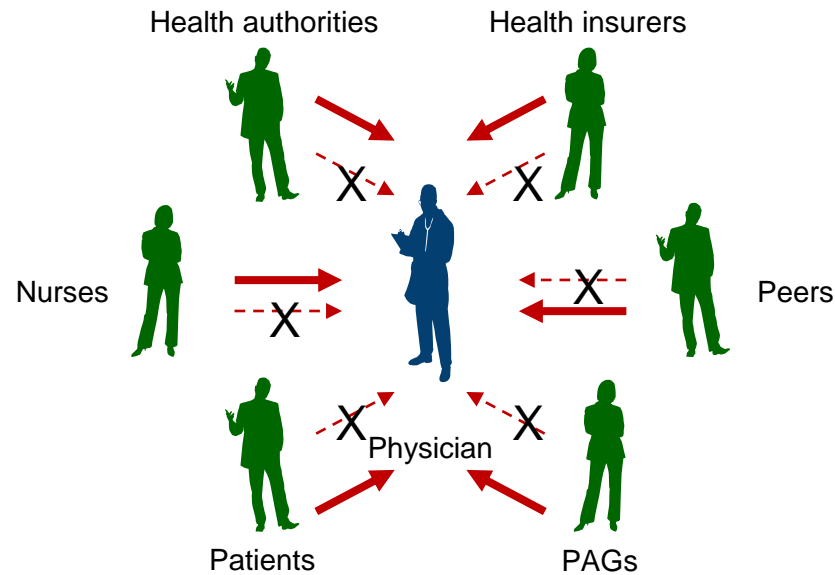
Sources: OECD Health Database as of February 2017 (Data 2015 excepted for Japan: 2014)

<sup>1</sup> Other expenditure include ancillary services (non-specified by function), preventive care & governance / health system / financing administration

The pharma market is increasingly driven by multiple stakeholders influencing physicians prescriptions and by secondary care drugs mainly prescribed at hospital

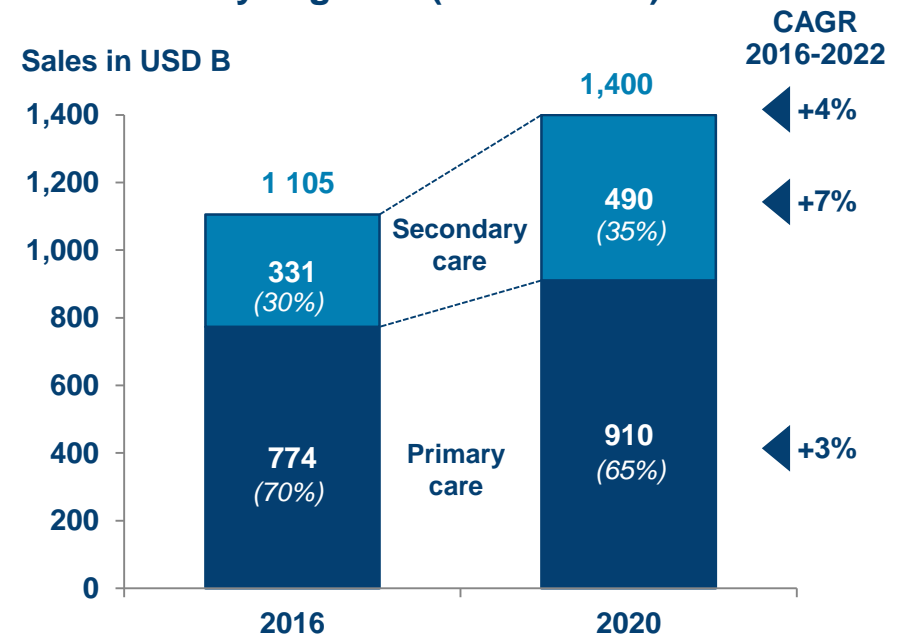
### Evolution of the pharma market structure

#### Therapeutic decision-making process evolution



Physician prescribing decisions are more and more under the influence of multiple stakeholders such as: national / regional health authorities, health insurers and payers, PAGs<sup>1</sup>, etc.)

#### Global pharmaceutical market growth by segment (2016 – 2022)



Secondary care products which are mainly prescribed<sup>2</sup> in hospital centers should grow faster than primary care products mainly initiated and prescribed by office-based physicians

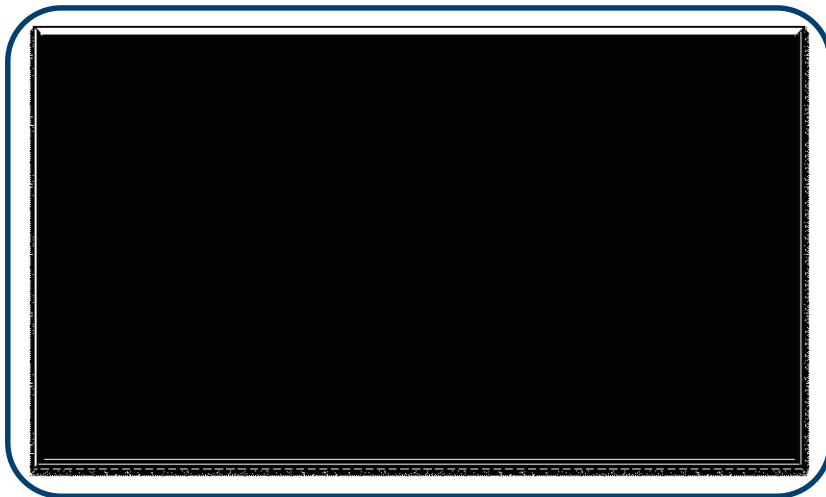
Sources: Smart Pharma Consulting estimates after: "Outlook for Global Medicines through 2021", Quintiles IMS (December 2016)

<sup>1</sup> Patient Advocacy Groups – <sup>2</sup> 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

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

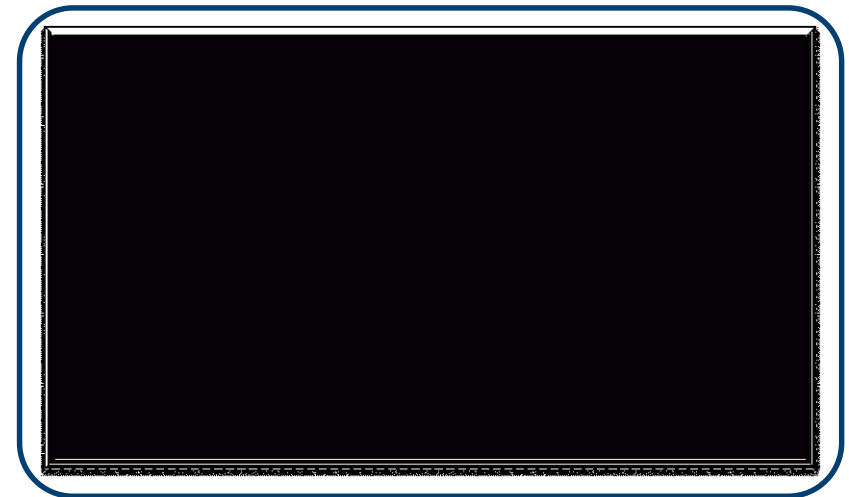
**Complexification and concentration of the business**

**Hospital market segment**



- Within hospital centers, physician prescribing decisions are more and more made in concertation, following protocols, and through the influence and pressure of various stakeholders, including payers
- Hospital centers are also regrouping themselves which increases their business importance and bargaining power

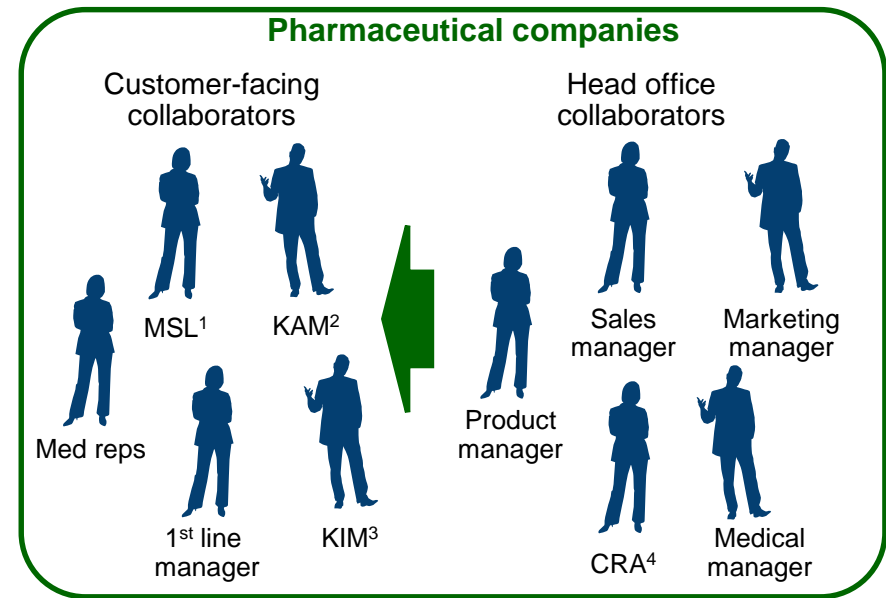
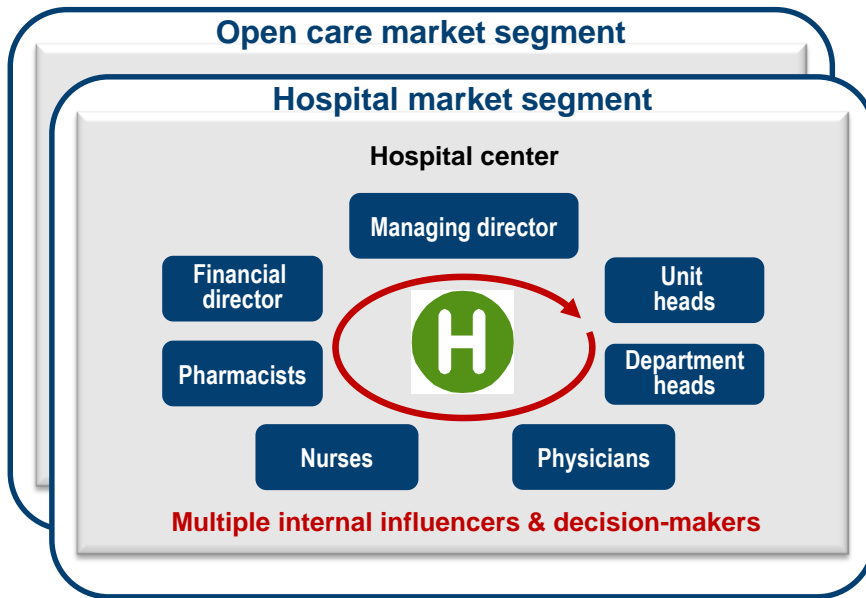
**Open care market segment**



- More and more office-based physicians work in group practice for better efficiency and practicality
- Besides, an increasing number of them belong to networks sharing similar therapeutic approaches and drug choices
- In the open care market, physicians make decisions in concertation with other HCPs or payers

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

### Implications for pharma companies



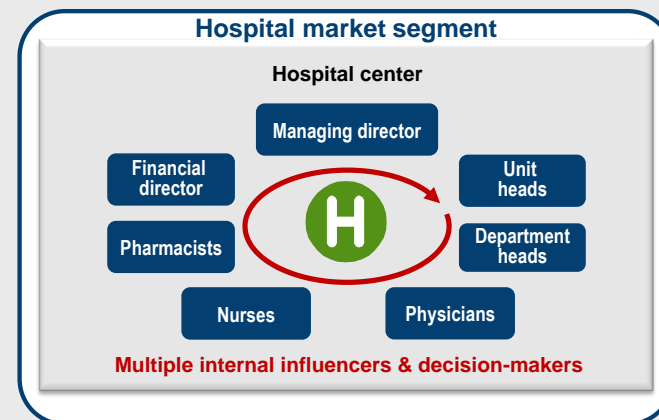
- The grouping of hospital centers and office-based physicians have led pharma companies to deal with bigger accounts benefiting from a stronger bargaining power...
- ... in a context of economic pressure, making customers more price-sensitive than ever

- Pharma companies 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

**With the consolidation of their customers becoming bigger and more price-sensitive, pharma companies have created KAM positions to better protect their business**

### Scope & Objective

- Suppliers of the FMCG<sup>1</sup> sector have created, long time ago, the position of **Key Account Managers** (KAMs) to better negotiate their global offering with the chains of distributors
- KAMs are not new in the pharma industry but their importance has recently increased to better cope with the increasing price-sensitivity, complexity and business importance of key accounts
- The purpose of this position paper is to introduce the **KAM EXPERT WHEEL** developed by Smart Pharma Consulting to **strengthen** the **competences** and **performance** of **KAMs**
- If this program, which includes **concepts**, **methods** and **tools**, has been specifically designed for **hospital** KAMs...
- ... **most** of its content **applies to other key accounts** such as:
  - Regional health authorities & payers<sup>2</sup>
  - Local health centers<sup>3</sup>
  - Pharmacy chains & VTOs<sup>4</sup>



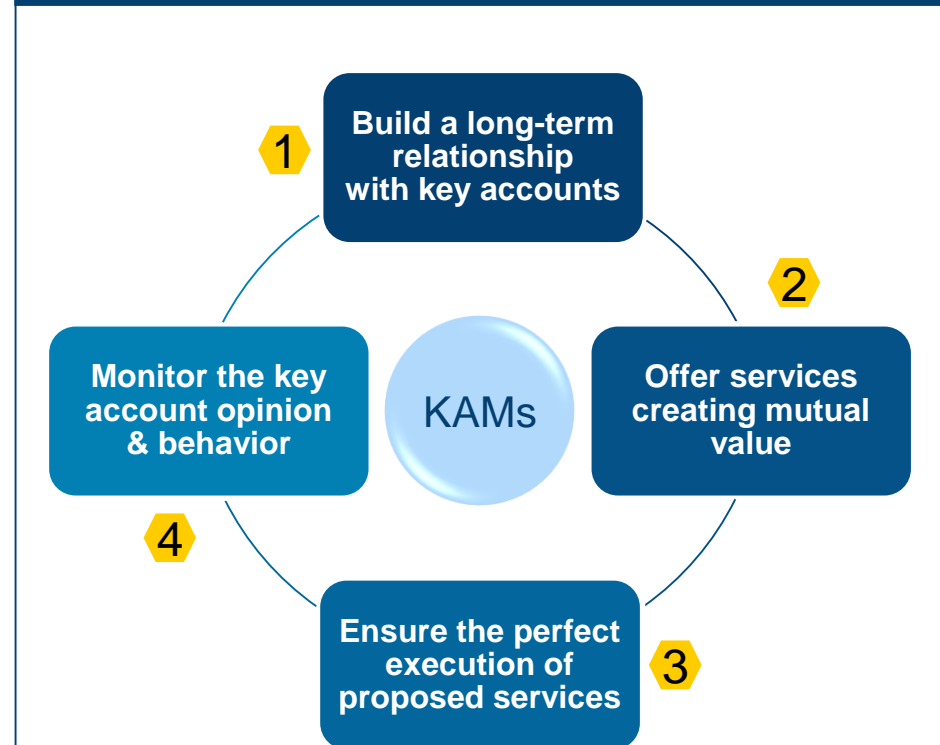
**Hospital Key Account Managers role is to influence multiple stakeholders in a complex B-to-B environment by creating long-term mutual benefits**

**Hospital Key Account Managers role and core activities**

**Role**

- KAMs are one of pharma companies' field teams<sup>1</sup> interacting with hospital centers
- Their role is to **develop the business** of pharma companies **over the long-term** by **proposing services** to hospital influencers and decision-makers to meet some of their needs, such as:
  - Become a reference center in a given pathology
  - Attract more patients
  - Improve hospital organization and efficiency (saving cost and time)
- KAMs have most often a **background of first-line manager**<sup>2</sup> and are in general **affiliated** to the **commercial department**
- Due to their cross-functional responsibilities beyond commercial matters, KAMs should ideally report to the head of the Hospital Division or to the COO<sup>3</sup>

**Core activities**





**Hospital KAM is a high level position requiring in-depth customer insights to determine their evolving needs and wants, and to propose solutions delivering mutual value**

### Hospital Key Account Managers core competences

**Competence = Knowing & Understanding x Deciding & Implementing**

#### Knowing & Understanding

- Set specific objectives per key account such as:
  - Getting listed
  - Modifying purchasing process
  - Minimizing price pressure
  - Gaining market share
  - Being prescribed to discharged patients
- Identify influence and decision paths at hospital level to secure the business of the pharma company
- Gather and analyze the needs and wants of key accounts to propose them services likely to create value to them, bearing in mind they can evolve overtime

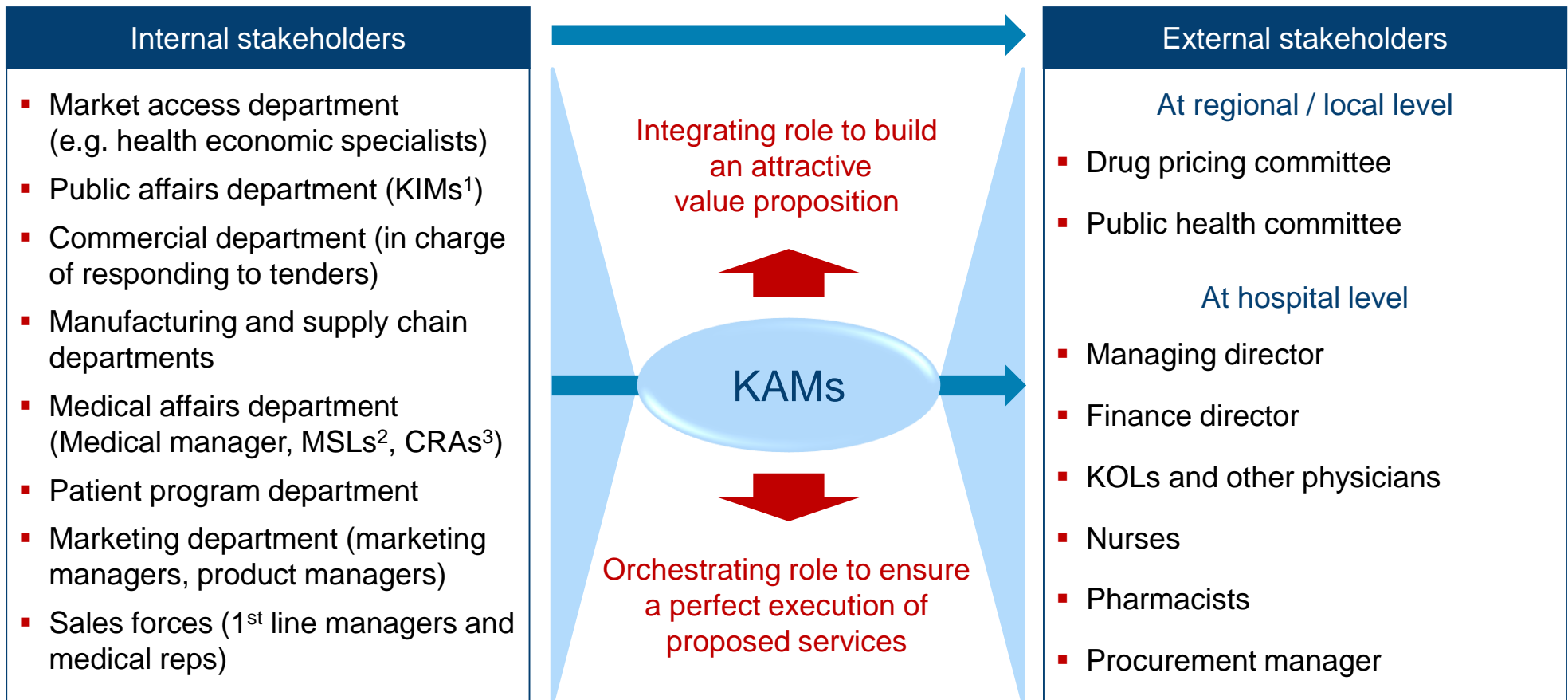
#### Deciding & Implementing

- Develop / co-develop<sup>1</sup> customized services associated (directly or indirectly) to the product portfolio which should deliver mutual value (benefit) for both the hospital and the pharma company
- Build a long-term relationship with key accounts
- Demonstrate leadership and ability to work with cross-functional and multidisciplinary teams
- Manage projects efficiently and effectively
- Monitor carefully the quality of execution and the impact of proposed services

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

**The complexity of the Hospital KAM role lies in the fact that they have to deal with multiple internal and external stakeholders having different needs and priorities**

**Cross-functional role of Hospital KAMs**



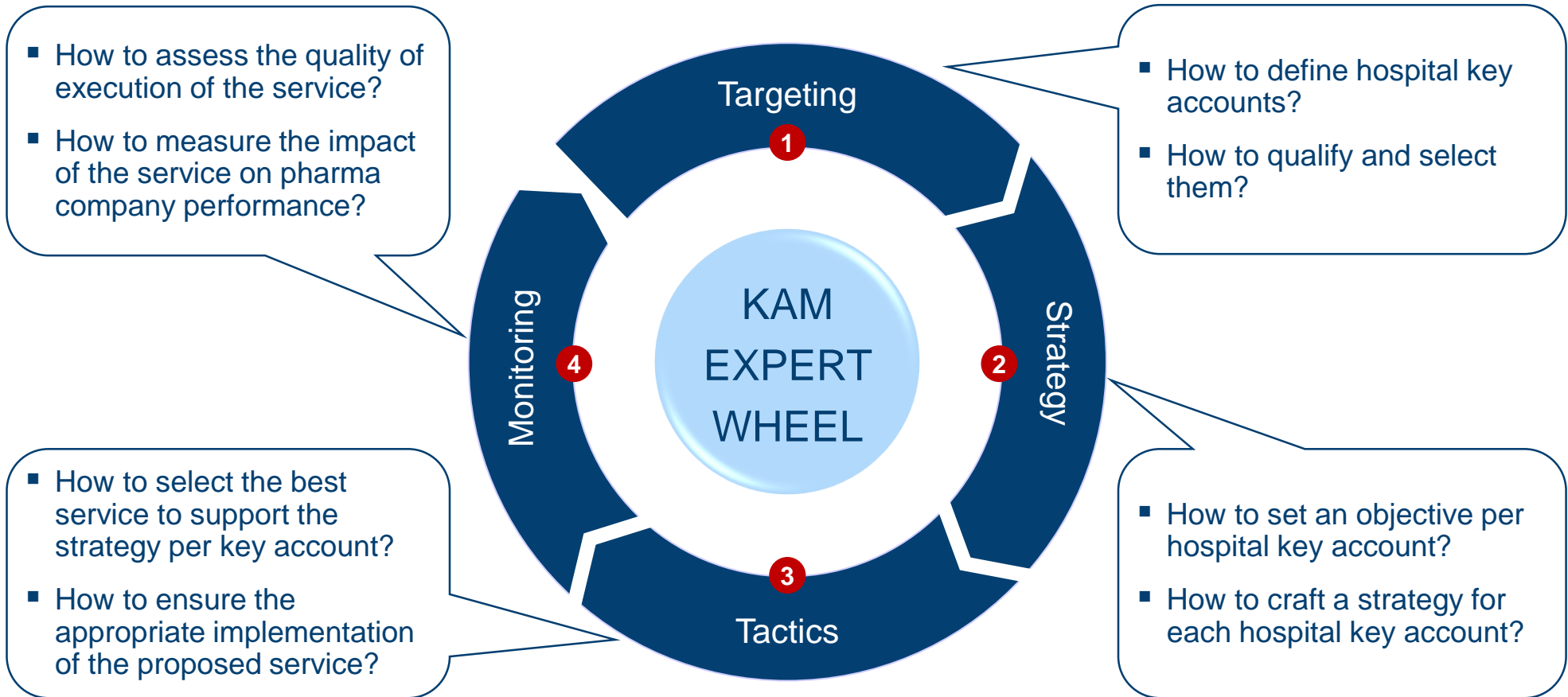
Sources: Smart Pharma Consulting

<sup>1</sup> Key Institution Managers in charge of relations with regional health authorities and payers –

<sup>2</sup> Medical Science Liaisons – <sup>3</sup> Clinical Research Assistants

**The KAM EXPERT WHEEL has been designed to structure the activities of the KAMs and help them cope with the complexity of their tasks**

**The four steps of the KAM EXPERT WHEEL**



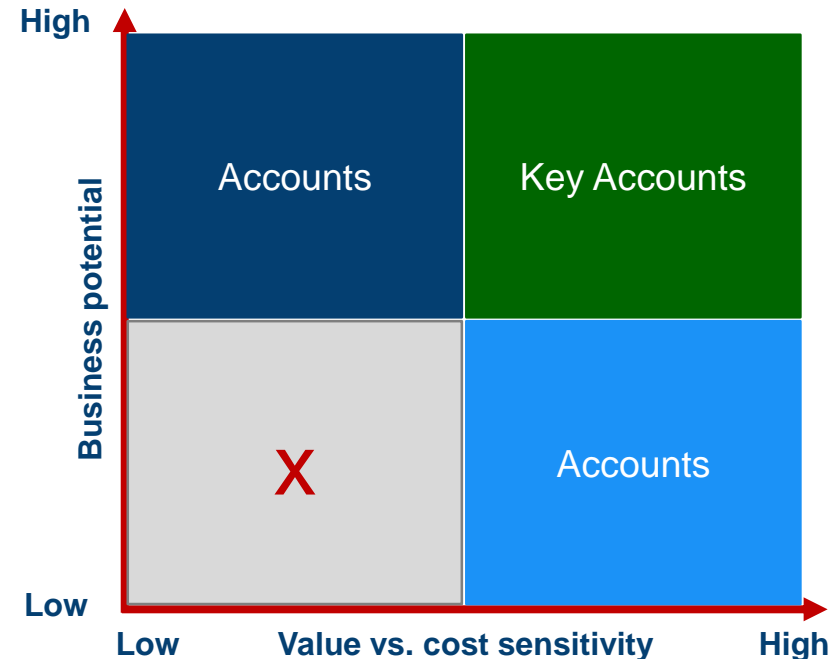
**Hospital key accounts should be critical to direct / indirect performance of pharma companies and value specific services associated to drugs, beyond their cost**

### How to define a hospital key account?

#### Specificities of Hospital Key Accounts

- To be eligible to the status of **key account** by a pharma company, hospital centers **should**:
  - Represent a **significant share** of its direct and/or indirect<sup>1</sup> sales and profits with **favorable perspectives**
  - Value solutions / services that could be proposed
- The **objective** of Key Account Management is to:
  - Optimize the performance (sales and profits) of the pharma company product portfolio (e.g. minimize price pressure, maximize sales level and growth)...
  - ... by **developing / co-developing services** to help hospital centers **meet their long-term objectives** (e.g. increase the number of patients, become a reference center, reduce management cost of medical procedures, simplify processes, etc.)

#### Hospital Key Account Targeting Matrix



**Beyond business potential, KAMs must estimate the propensity of hospital centers to “reward” pharma companies having delivered extra value to them through services**

**How to qualify and select hospital key accounts? (1/2)**

**Business potential**



- Before deciding to invest in services “around” their product portfolio, KAMs should carefully evaluate the long-term business potential (opportunities and threats) of hospital centers in the therapeutic areas covered by their product portfolio
- The following indicators will be useful to evaluate each account:
  - Five- to ten-year development plan of the hospital activities
  - Number of beds and healthcare professionals
  - Number of patients on the active list
  - Current and forecasted sales in the therapeutic areas covered
  - Level of inpatients and outpatients prescriptions and sales<sup>1</sup>
  - Influence of hospital prescribing habits on office-based physicians
  - Etc.
- To document these indicators, the KAMs must carry out desk research, interview regional health authorities, hospital managers, etc.; and then analyze the information gathered

## KAMs should carefully analyze each hospital center to determine its long-term business potential for their product portfolio with specific assessment tools

### How to qualify and select hospital key accounts? (2/2)

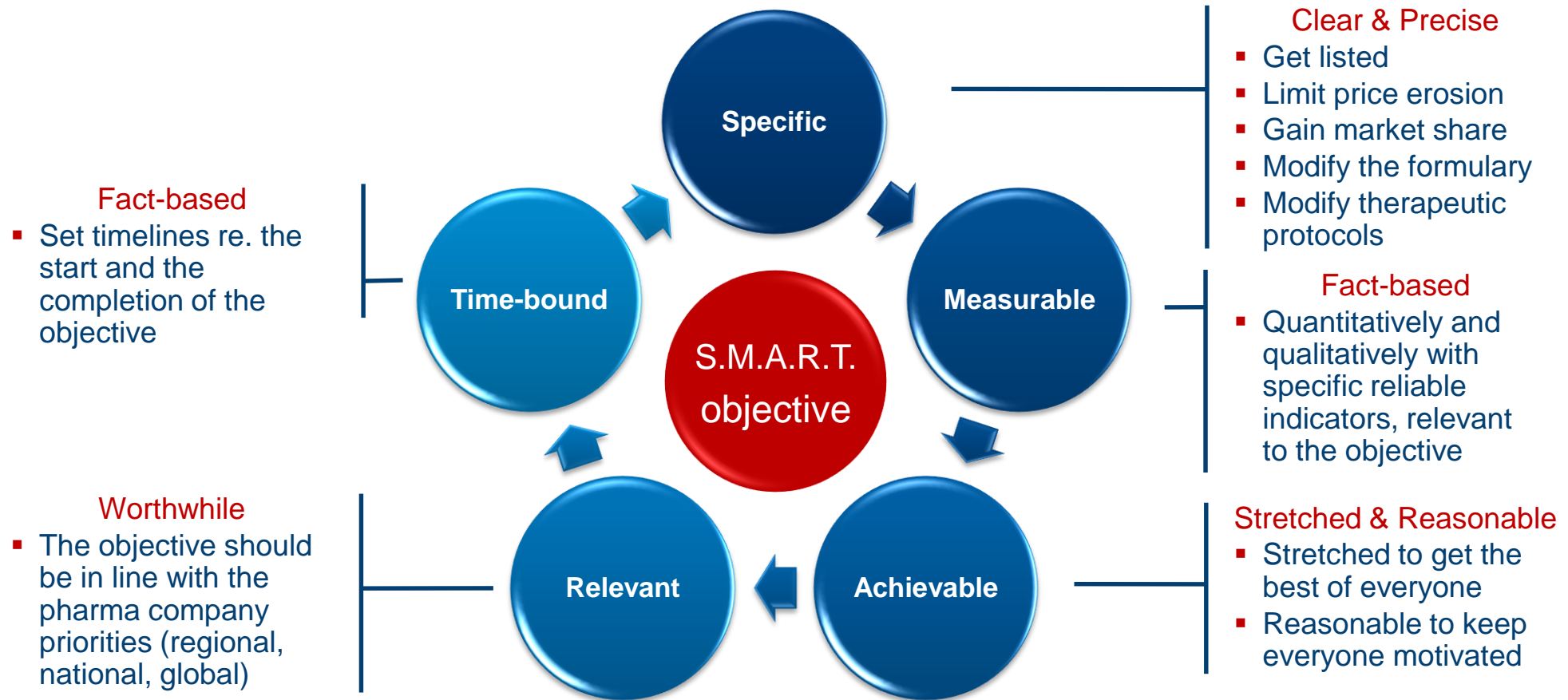
- Once the business potential has been estimated, KAMs should evaluate:
  - Hospital center needs for tailored services
  - Probability they accept to partner with a pharma company to develop and implement solutions
  - Value they will grant to these solutions
  - Rewards they will accept to give to the pharma company
- Developing and implementing solutions likely to create high value for key accounts require, in general, heavy investments for several years
- The relevance of such investments should be determined by their:
  - Suitability with assessment tools (e.g. SWOT chart) to evaluate losses and/or profits opportunities for the pharma company
  - Acceptability with analytical tools measuring their expected benefits (e.g. ROCE<sup>1</sup>, DCF<sup>2</sup> / NPV<sup>3</sup>, payback, risk sensitivity analysis)
  - Feasibility of the services / solution likely to be proposed on a financial (cash flow), regulatory (compliance) and practical (skills, competence, resources) point of view

#### Value vs. cost sensitivity



To set an objective per hospital key account, the well-know S.M.A.R.T. rules should be carefully applied to facilitate the proper crafting of the corresponding strategy

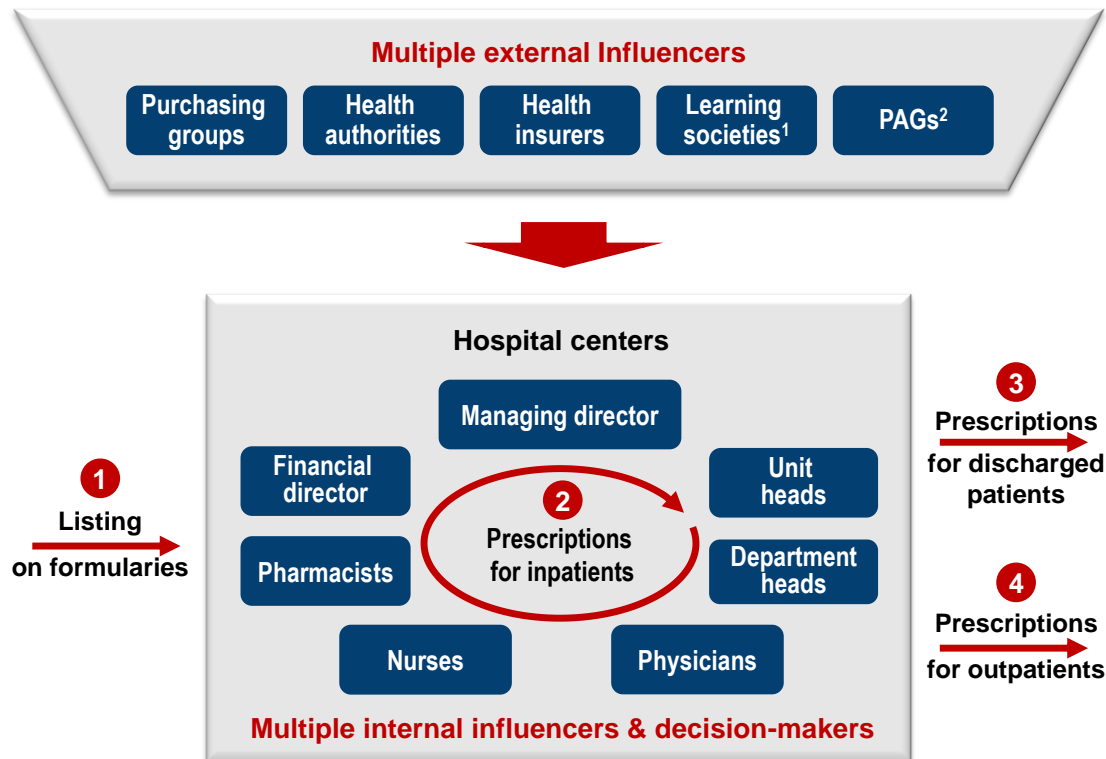
**How to set an objective per hospital key account?**





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

### How to craft a strategy per hospital key account? – Principles (1/2)



● Key performance drivers for pharma companies

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

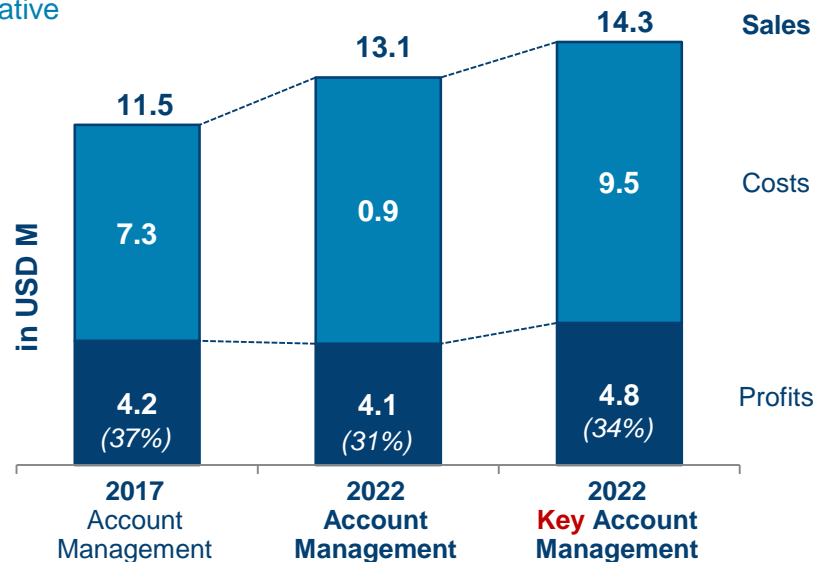


## To get the expected return on investment from hospital key account management, pharma companies should focus on five critical success factors

### How to craft a strategy per hospital key account? – Principles (2/2)

Expected impact from pharma company perspective

Illustrative



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

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<sup>1</sup> and KPIs<sup>2</sup> to deliver the expected joint value
- **#4:** The services should be clearly communicated by the KAMs and related to the pharma company and its product portfolio
- **#5:** KAMs should be empowered and able to coordinate cross-functional multidisciplinary internal and external stakeholders

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

## How to craft a strategy per hospital key account? – Tools (1/2)

### Integrated Key Account Management Plan

#### MSL<sup>1</sup> Section

- Key clients: KOLs
- Key objectives: build strong and sustainable relationships to develop advocacy at the 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.



#### Marketing & Medical Rep Section

- Key clients: physicians and pharmacists
- Key objectives: Increase prescription share
- 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

#### Key Account Manager Section

- Key clients: health authorities<sup>2</sup>, payers<sup>2</sup>, hospital directors, hospital purchase managers, etc.
- Key objectives: strengthen the sales and profits of the product portfolio per hospital center
- Key activities: propose / co-develop specific “win-win” projects (e.g. medico-economic studies to increase the access to the brands, patient support programs to improve adherence to treatment, etc.)<sup>3</sup>

**KAM activities should be formalized in an Integrated Key Account Management Plan per hospital center, in coordination with medical, marketing and sales collaborators**

**How to craft a strategy per hospital key account? – Tools (2/2)**

**Integrated Key Account Management Plan**



**Structure of the KAM section**

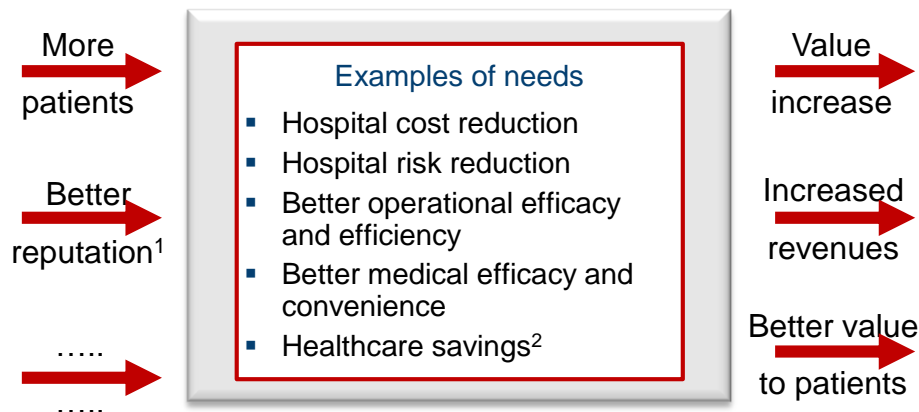
- **Situation analysis (per hospital center)**
  - Mapping of key stakeholders (level of influence – behavior)
  - Activity review (quantitative and qualitative analyses):
    - Relationships with key stakeholders (e.g. managing director, financial director, procurement manager, hospital pharmacists, heads of medical departments) of each hospital center re. services currently in place and the needs for new ones
    - Offering / development of services creating mutual value
    - Ensuring the perfect execution of services
    - Monitoring of opinion and behavior of stakeholders
  - Quality of execution and impact of activities measurement
  - Advanced SWOT<sup>1</sup> analysis of the KAM and his pharma company
- **Ambition & strategic priorities (per hospital center)**
  - Ambition setting
  - Strategic priorities to fulfill mid- to long-term ambitions set by the KAM
  - Key activities to support strategic priorities:
    - Shared activities with other departments (e.g. marketing, sales, MSLs, etc.)
    - Non-shared activities
  - Selection of KEIs<sup>2</sup> and KPIs<sup>3</sup> to monitor the services proposed

**The services proposed by KAMs should fulfill highly valued customer needs and thus contribute to strengthen the business performance of the pharma company**

**How to select the best services to support the strategy? – Principles**

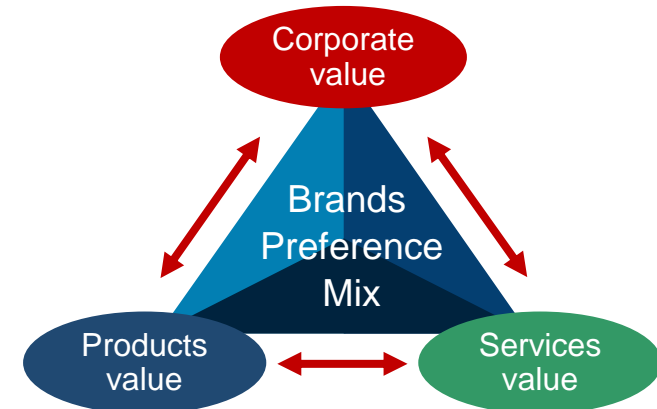
Examples of potential hospital center highly valued needs

**Hospital center**



- Pharma companies may create great value for hospital centers by helping them:
  - Reduce their costs (e.g. procurement process)
  - Manage their risks (e.g. preparation of chemotherapies)
  - Improve their operational efficacy and efficiency (e.g. reallocation of resources, process simplifications)
  - Increase their medical efficacy (e.g. modify protocols) and convenience (e.g. better patient quality of life)

Potential impact of services on pharma company performance

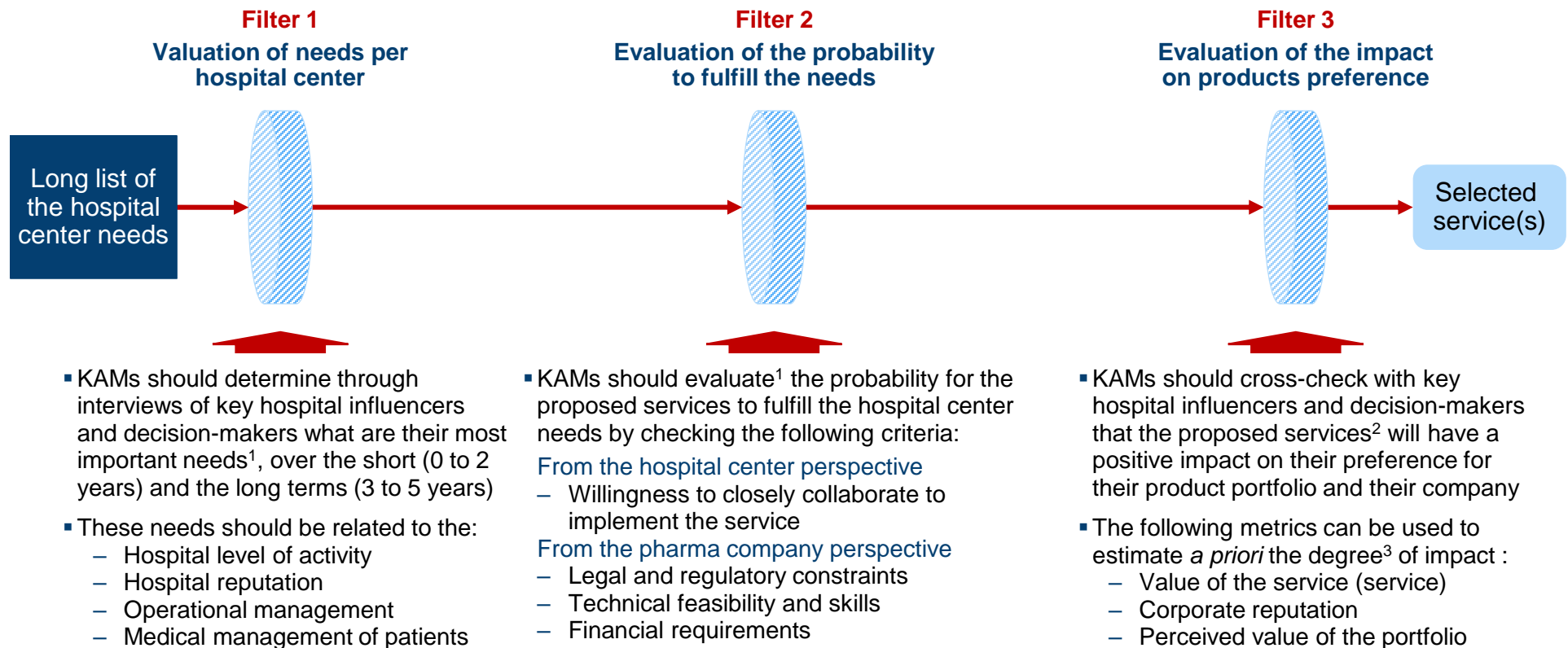


- By offering services – fulfilling hospital centers highly valued needs – pharma companies can expect to:
  - Improve their corporate reputation and
  - Strengthen the perception of their product portfolio and thus, be preferred at the expense of their competitors (i.e. increased likelihood of being listed, better price, higher prescription rate for inpatients and out-patients)

**KAMs should ensure that the selected hospital needs they intend to fulfill are highly valued and the probability to fulfill them is high to expect a return on investment**

**How to select the best services to support the strategy? – Method**

Selection of most appropriate services to meet hospital center and pharma company respective objectives



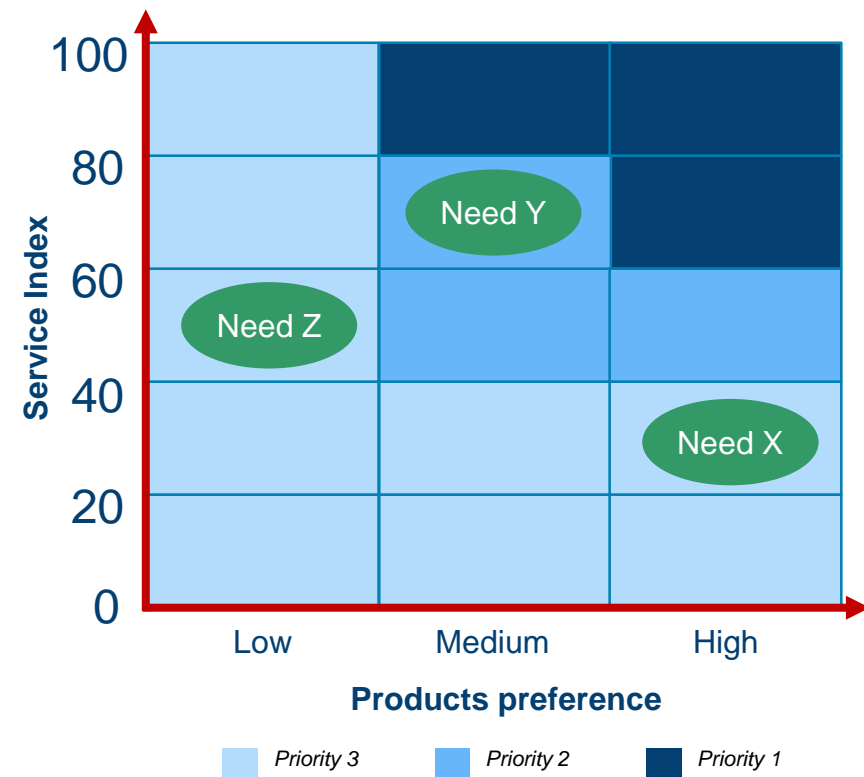
The assessment chart and the selecting map can help KAMs figure out which service they should preferably commit to offer to individual hospital key account

### How to select the best services to support the strategy? – Tools

Assessment chart<sup>1</sup>

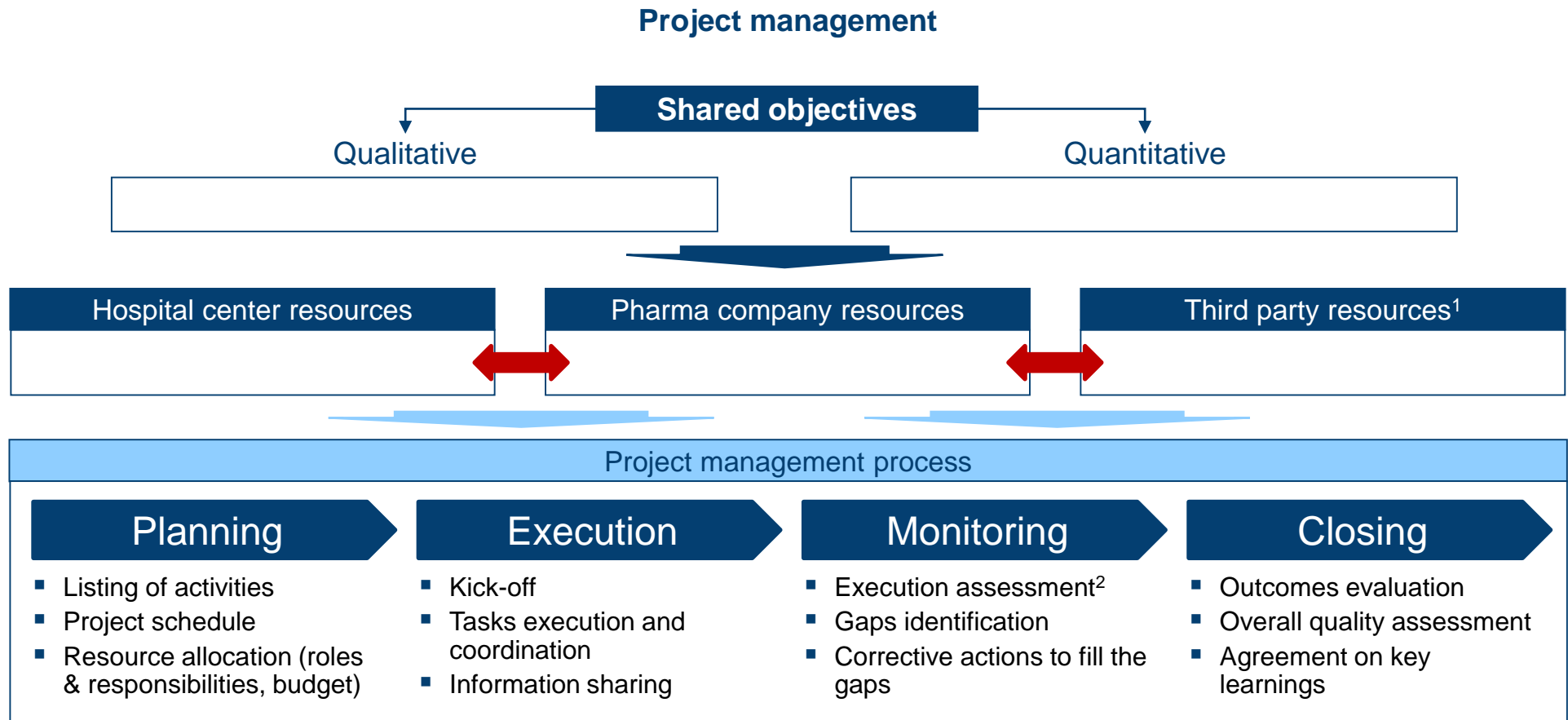
List of hospital center needs	Need X	Need Y	Need Z	-----
A. Valuation of needs	7	8	8	-----
B. Probability of fulfilling these needs	5	8	6	-----
C. Service Index (AxB)	35	64	48	-----
D. Likely impact on products preference	High	Medium	Low	-----

Selecting map



**It is essential to follow a rigorous project management process to ensure the smooth implementation of the services and increase the chance to get the expected results**

**How to ensure the appropriate implementation of the proposed services? – Method**



The “Hospital Service Card” is an enabling tool to ensure that hospital stakeholders and the pharma company are aligned on the purpose of the proposed service(s)

**How to ensure the appropriate implementation of the proposed services? – Tool**

**Hospital Service Card (HSC)<sup>1</sup>**

Hospital center name and address		Hospital center key stakeholders		Key issues	
Hospital key activities		Hospital center project manager <sup>2</sup>		Key needs	
Hospital influence		Pharma company KAM <sup>3</sup>		Key wants	

Description of the proposed service					
Objective of the service	For the hospital center		For the pharma company		
Duration of the service	Start date		End date		

Sources: Smart Pharma Consulting

<sup>1</sup> If several services are proposed for the same hospital center, thus several HSC should be filled up –

<sup>2</sup> Key contact point regarding the partnership and the service(s) included in this partnership –

<sup>3</sup> In charge of the service(s) proposed to the hospital center



**The services proposed must create tangible value to the most powerful individuals to increase access and usage of the product portfolio within the hospital key account**

**– Examples of potentially highly valued services by hospital centers and pharma companies –**

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

The quality of execution of the service should be subject to a dual assessment by the hospital center which benefits from it and the pharma company which proposes it

### How to assess the quality of execution of the services? – Tool

Service description		Service objective		Hospital center stakeholders	
Dual valuation by the partners (key hospital stakeholders & pharma company)					
Valuation of the Service*		Rationale	Valuation of the Execution*		Rationale
Impact on hospital costs	1 2 <b>3</b> 4 5		Quality of planning	1 2 <b>3</b> 4 5	
Impact on operational management	1 2 <b>3</b> 4 5		Quality of execution	1 2 <b>3</b> 4 5	
Impact on medical (patient) management	1 2 <b>3</b> 4 5		Quality of monitoring	1 2 <b>3</b> 4 5	
Impact on healthcare savings	1 2 <b>3</b> 4 5		Quality of budget control	1 2 <b>3</b> 4 5	
Gap analysis		Recommendations	Gap analysis		Recommendations

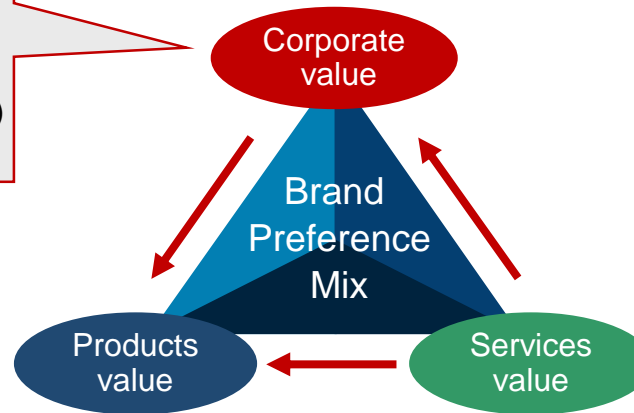
**From the pharma company perspective, the value of the proposed services should be translated into higher product sales and associated profits**

**— How to measure the impact of the services on pharma company performance? – Method —**

The ultimate objective of the services proposed to the hospital key account is to fulfill one of its highly valued needs to enhance its preference for the product portfolio marketed by the pharma company

- The KAM should communicate once or twice a year information about his company (e.g. R&D news, CSR<sup>1</sup> initiatives, specific services delivered, etc.) to the hospital stakeholders

- The direct or indirect<sup>2</sup> impact of services on the pharma company will be objectivized by the positive evolution of its performance drivers:
  1. Listing on formularies
  2. Prescription for inpatients
  3. Prescription for discharged patients
  4. Prescription for outpatients within the hospital key account

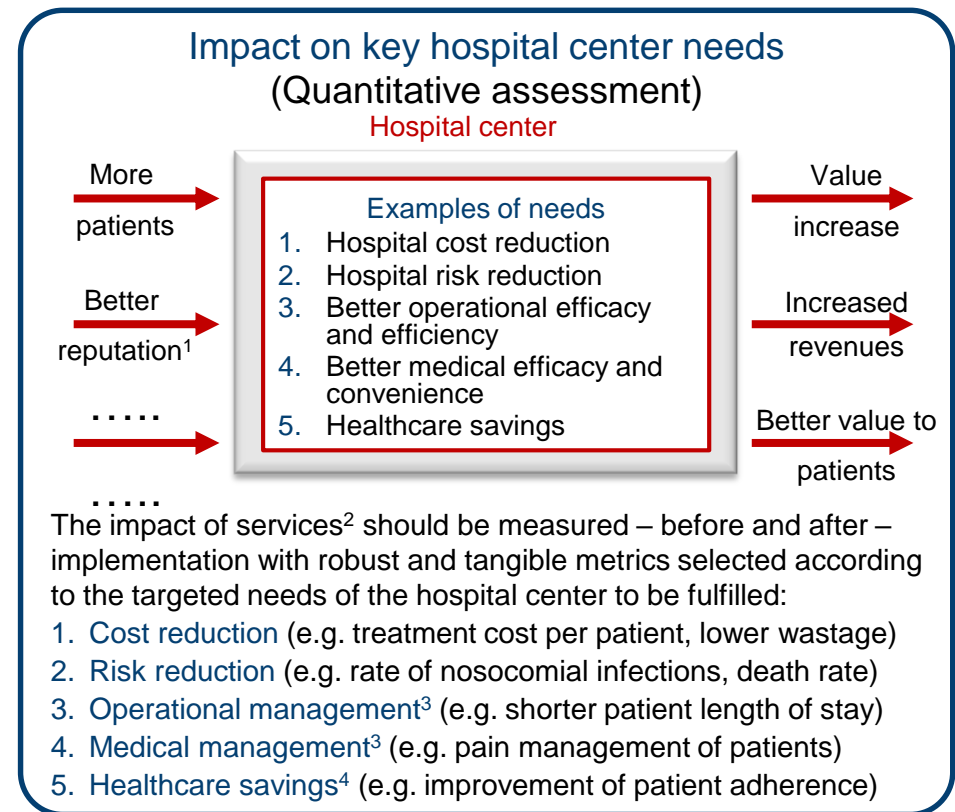
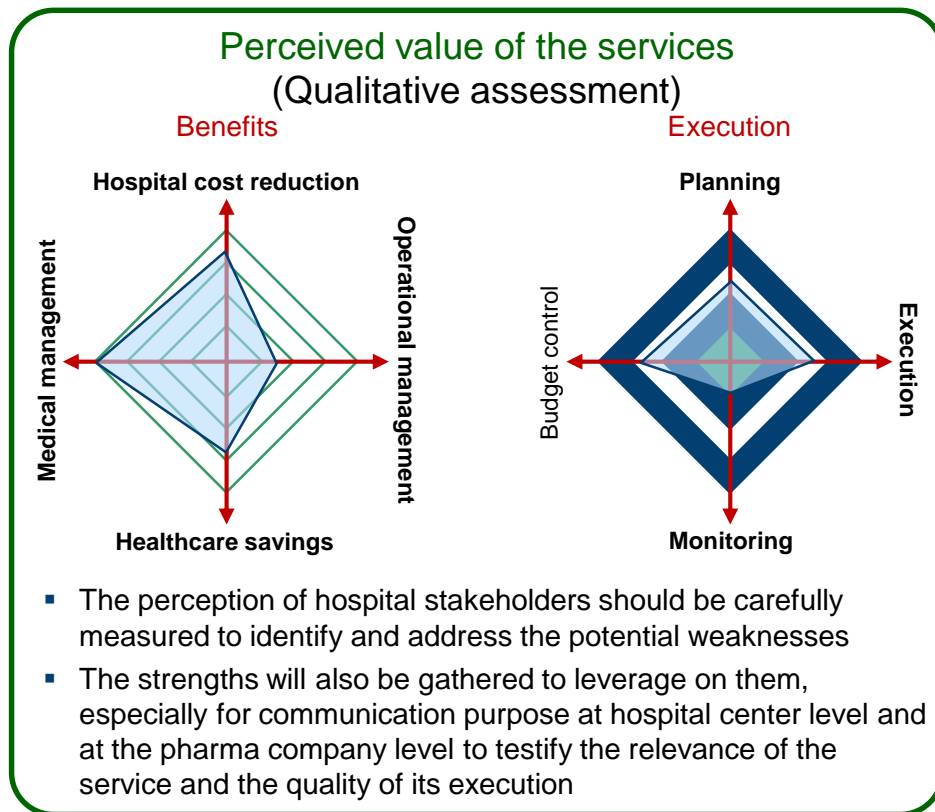


- The perceived value of the proposed services by the hospital key account will depend on their ability to:
  - Reduce hospital costs
  - Improve operational management
  - Improve medical management...
- ... and on their quality of execution:
  - Planning
  - Execution *per se*
  - Monitoring
- These services should have a positive impact on corporate reputation and products perception

To objectivize the benefits provided by the services to hospital centers, metrics based on tangible and robust data should be selected and agreed upon *a priori*

## Measurement of service value for hospital centers – Tools (1/2)

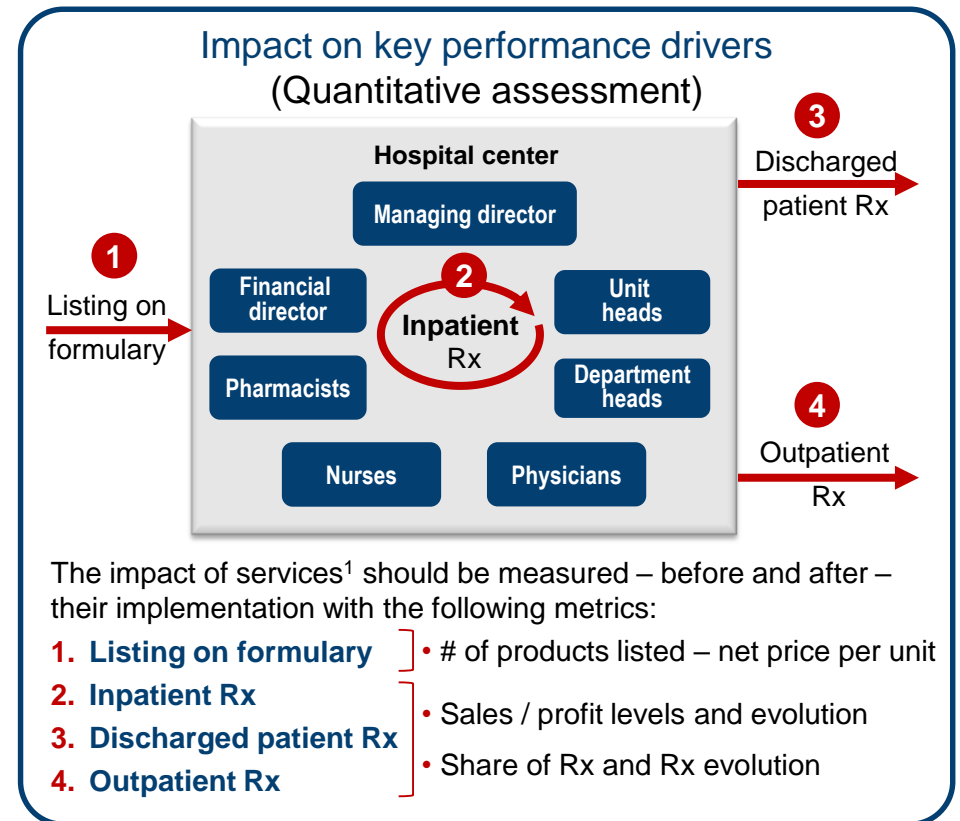
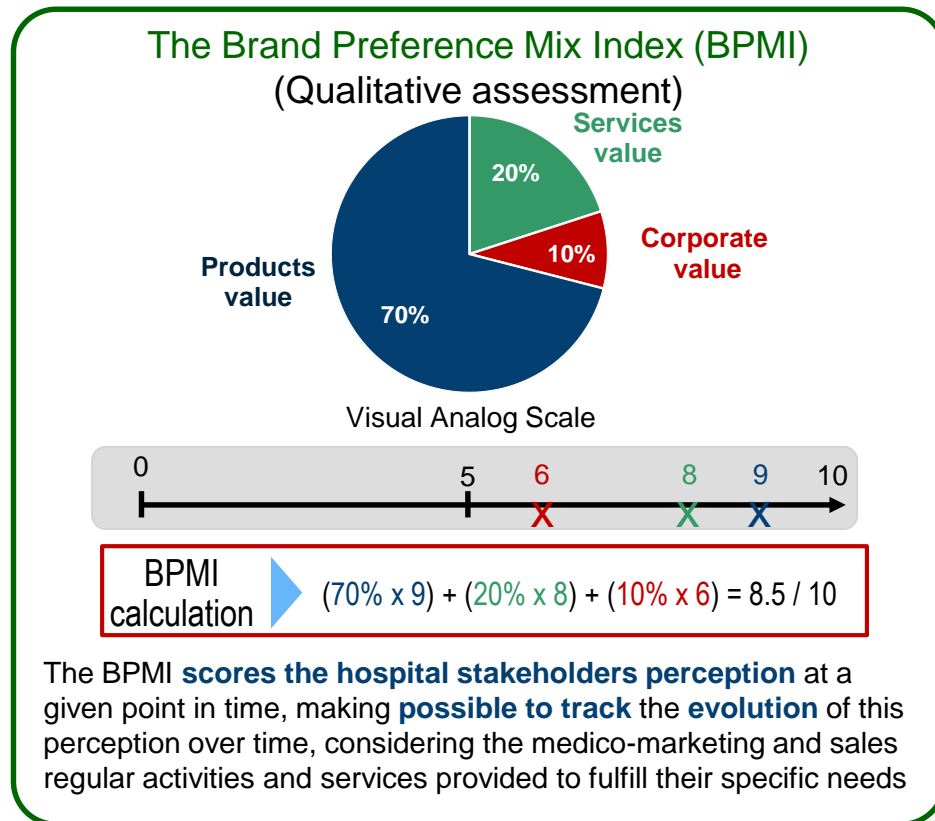
### Qualitative and quantitative assessment tools



The impact of services proposed by the KAMs to hospital centers should be carefully measured with qualitative and quantitative metrics as proposed here-below

— **Measurement of the impact of services on pharma company performance – Tools (2/2)** —

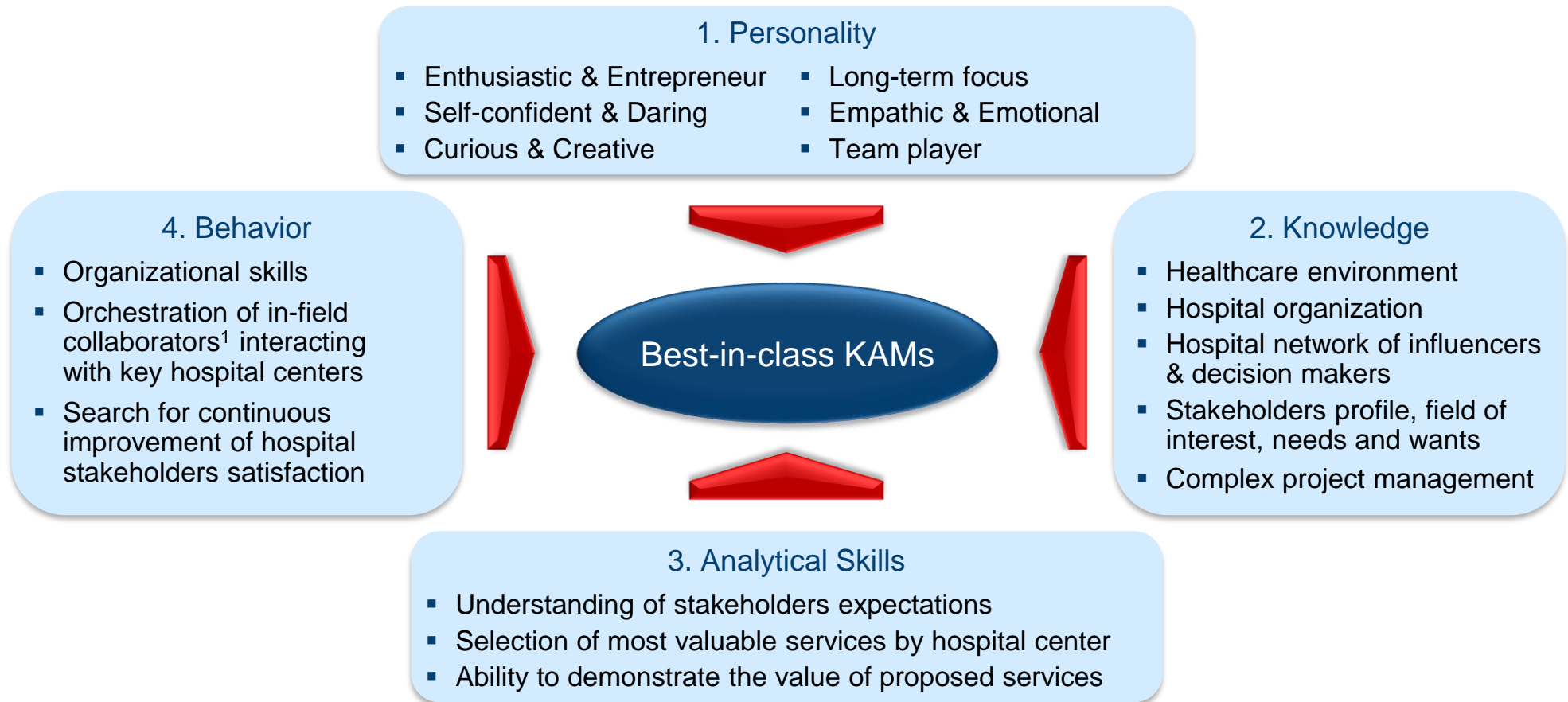
Qualitative and quantitative assessment tools



● Key performance drivers for pharma companies

**KAMs must have an in-depth understanding of hospital center organizations and needs, be able to manage cross-functional teams and to build trusted long-term relationships**

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



**Irrespective of their competence, KAMs should dramatically improve their performance if they implement the KAM EXPERT WHEEL in a rigorous and systematic way**

### KAM EXPERT WHEEL implementation



#### The key success factors

1. Carefully **define** hospital **key accounts** according to:
  - The **business potential** they represent for your current and future products
  - The **importance** they attach to **services** provided by **pharma companies** to **avoid investing at loss**
2. Set a **shared objective** with each key account which, if reached, is likely to **lead** to “win-win” **outcomes** for both parties
3. The proposed **services** should **fulfill important needs / wants** of the hospital key stakeholders and contribute to **strengthen** the pharma company **performance**
4. While **executing** the service, it is **essential** to:
  - **Communicate internally** (to keep informed and aligned the collaborators in contact with the hospital center) and **externally** (to ensure that the key hospital stakeholders link the service with the pharma company and its product portfolio)
  - Comply with the **highest standards** of **quality**
  - **Measure** the **value** (benefit) of the **services** for the **hospital centers** and their **effect** on the pharma company **business performance**

**As the author of the KAM Expert Wheel and considering their operational experience, Smart Pharma consultants are well positioned to facilitate its implementation**

### **KAM EXPERT WHEEL implementation**

- Smart Pharma Consulting has an **in-depth expertise** in **improving efficiency of in-field teams** coming from:
  - **General management experiences** in France and abroad for pharma companies
  - **Numerous** operational effectiveness consulting **projects** on the hospital pharma market segment
- The KAM EXPERT WHEEL which has been developed by Smart Pharma Consulting proposes a **rigorous** and **practical** approach to **obtain** a significant **improvement** of **KAMs efficiency** and **efficacy**
- Smart Pharma Consulting can help pharma companies introduce the KAM EXPERT WHEEL as follows:

3. **Support methodologically** and with specific tools the **selection of services** per hospital key account
4. **Develop tools** to **assess the quality of execution** of the **services proposed**...  
... and to **measure their impact** on pharma company performance



1. **Customize** the proposed **targeting method** and **tools** to the specific context of the **pharma company**
2. **Help setting objectives** per hospital key account and **craft** an appropriate **strategy** (incl. the **design** of specific **hospital key account management plans**)





BD&L opportunities being rare and complex, Pharma BD&L managers would be well-advised to adopt a systematic, rigorous and perfectly planned approach

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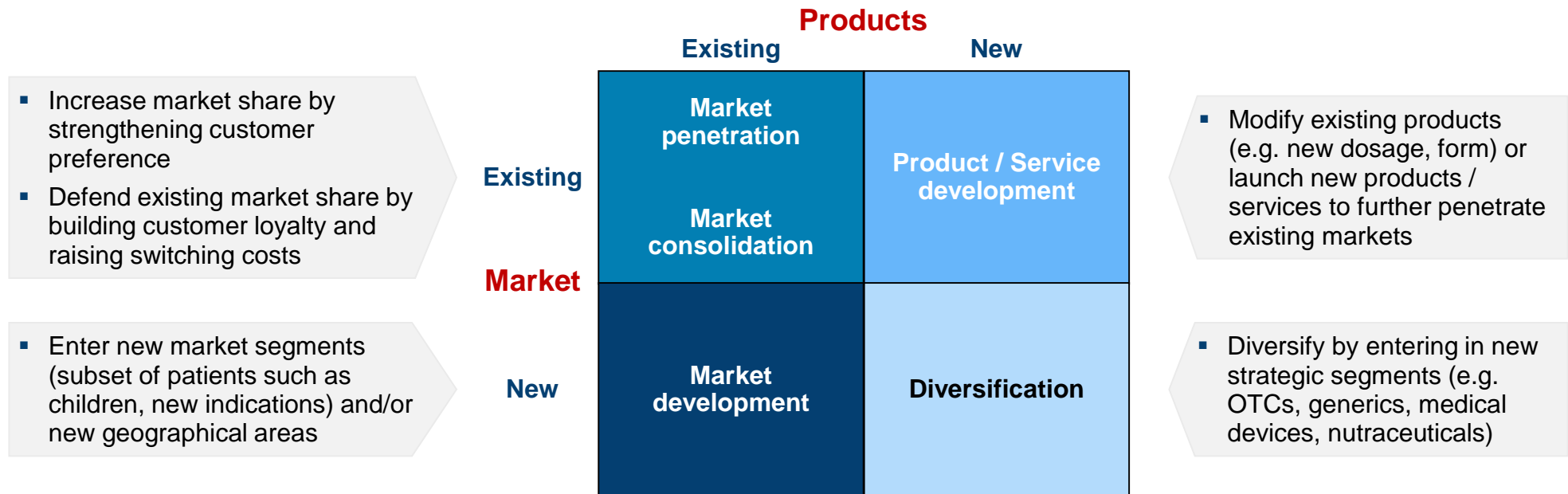
**Key points addressed**

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- What is the **purpose** of BD&L?
- What are the most common **types of BD&L deals**?
- How to **assess** BD&L **opportunities**?
- How to **formalize** a BD&L **strategy**?
- How to **approach target companies** for BD&L opportunity?
- How to **assess** and **select a product** eligible for BD&L deal (application)?

## Four basic strategic directions can be pursued by affiliates of pharmaceutical companies to boost their strategic development

### Alternative directions to ensure strategic development



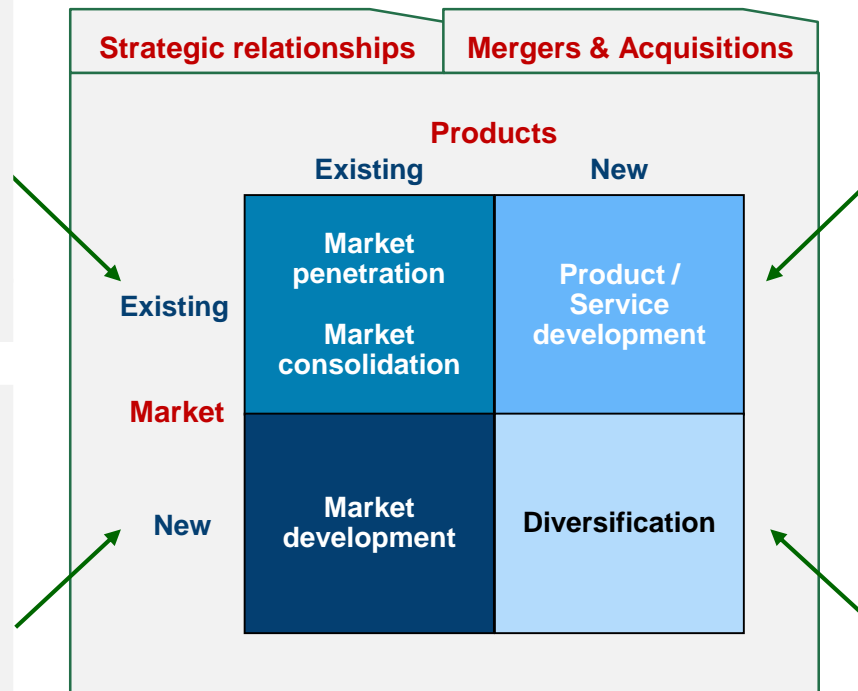
Sources: Adapted by Smart Pharma Consulting from H. Ansoff

**BD&L refers to strategic relationships or Merger & Acquisition deals which enable affiliates to grow and strengthen their competitive position**

### Definition of BD&L

- Collaboration with a third party (e.g. pharma company, CSO<sup>1</sup>) to increase share of contacts and/or share of voice
- Co-marketing or co-promotion agreements to increase resources behind one molecule
- Acquisition of competitors to reduce or better manage competitive intensity

- Collaboration with a CRO<sup>2</sup> to develop new indications
- Co-promotion with a partner to promote to a group of new clients (e.g. pediatricians, neurologists)
- Licensing-out to a third party to:
  - Market in new countries (e.g. biotech products in Africa)
  - Expand presence in second priority territories (e.g. in Mexico, South Africa, India)
  - Etc.

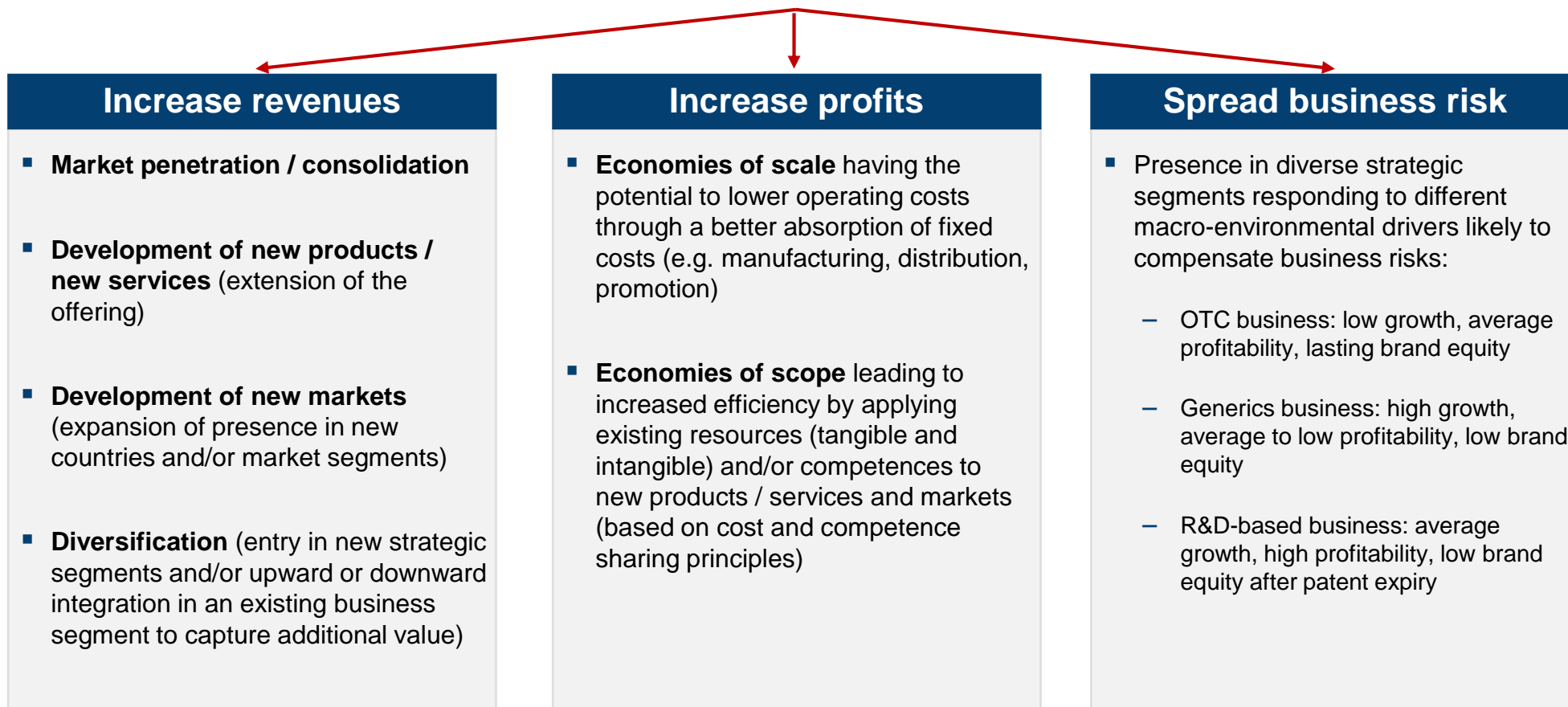


- Outsourcing development of a new combined formulation
- Co-branding of a diagnostic tool and of a drug for a given pathology (e.g. diabetes, hypertension, oncology, etc.)
- Co-development of back-up brands (i.e. isomers, active metabolites, esters, salts of existing molecules)
- Acquisition or in-licensing of new drug delivery systems

- Acquisition, merger, joint-venture or in-licensing deals to enter in:
  - A new strategic segment (e.g. OTC, generics, home care services, etc.) or therapeutic domain (e.g. neurology) through horizontal integration
  - Distribution business through downward integration
  - Toll manufacturing business through upward integration
  - Etc.

**BD&L initiatives are expected to generate extra revenues, increase profits and/or spread business risk, while leveraging potential synergies**

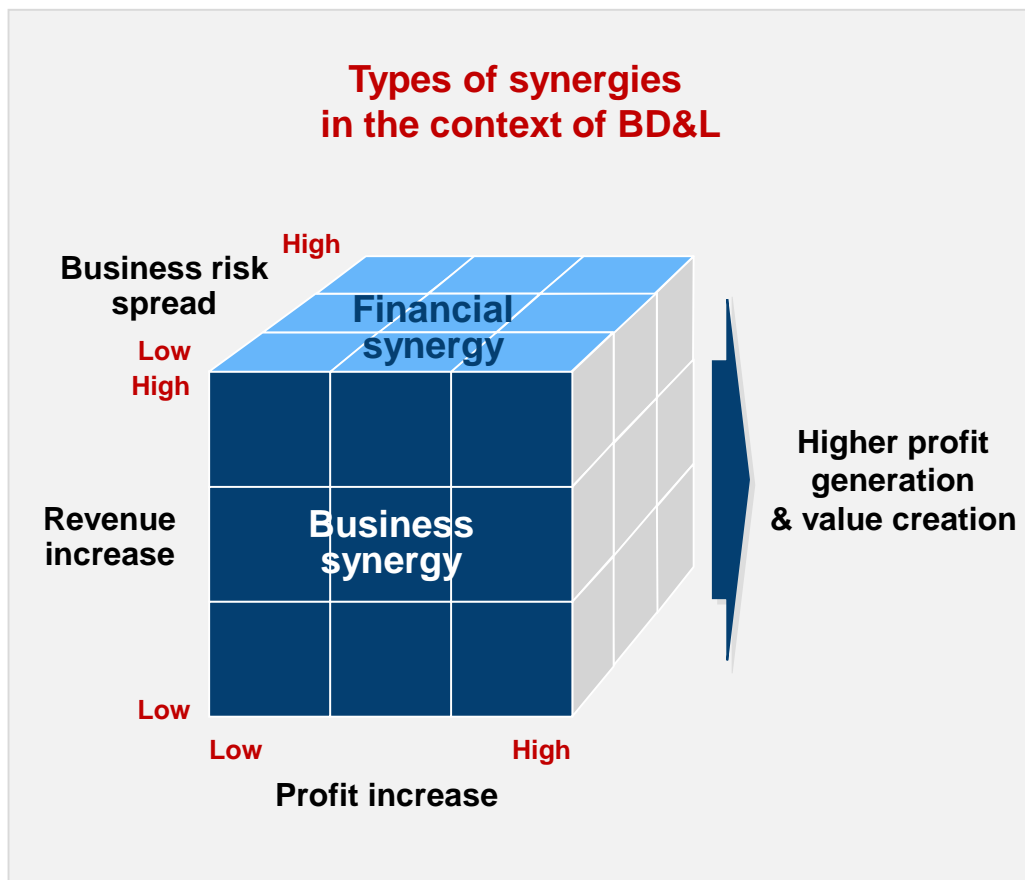
**Expected benefits from BD&L initiatives**



Sources: Smart Pharma Consulting analysis

**Synergies result from a better mixing and matching of capabilities, and are the greatest when opportunities are in businesses similar to those in which affiliate operates**

**Concept of synergy applied to business development**



**Comments**

- Synergy refers to the benefits gained when activities or assets complement each other so that their combined effect is greater than the sum of the parts
- Synergies are supposed to generate higher profits and/or enhance value through:
  - Revenue increase with  $1+1>2$
  - Cost reduction with  $1+1<2$
- There are two different types of synergies:
  - Business synergies due to cost reduction and/or revenue increase through combination of capabilities (i.e. tangible / intangible resources and competences)
  - Financial synergies related to possible spread of business risks if combined strategic segments are subject to different opportunities and threats
- Positive synergies are based on:
  - Shared competences (economies of scope)
  - Shared costs (economies of scale)
- Negative synergies refer to lower profit generation and value destruction:
  - Revenue increase (or even decrease) with  $1+1<2$
  - Cost increase with  $1+1>2$

resulting from complexity, mismanagement, problems of integration, lower efficiency, brand cannibalization, etc.

## Strategic relationships and M&A may contribute to build capabilities and create business synergies, but not without difficulties and risks

### Capability building through business development

#### Strategic relationships

- Strategic alliances involve the sharing of capabilities (resources + competences) in pursuit of common goals
- Outsourcing, which is a form of subcontracting, enables affiliates to access capabilities by borrowing them from other companies (e.g. deals with a CSO<sup>1</sup> or another pharma company)
- Accessing capabilities through alliances offers more targeted and cost effective means than acquisition
- Where both partners are trying to acquire one another's capabilities, results may be a "competition for competence" that ultimately destabilizes the relationship

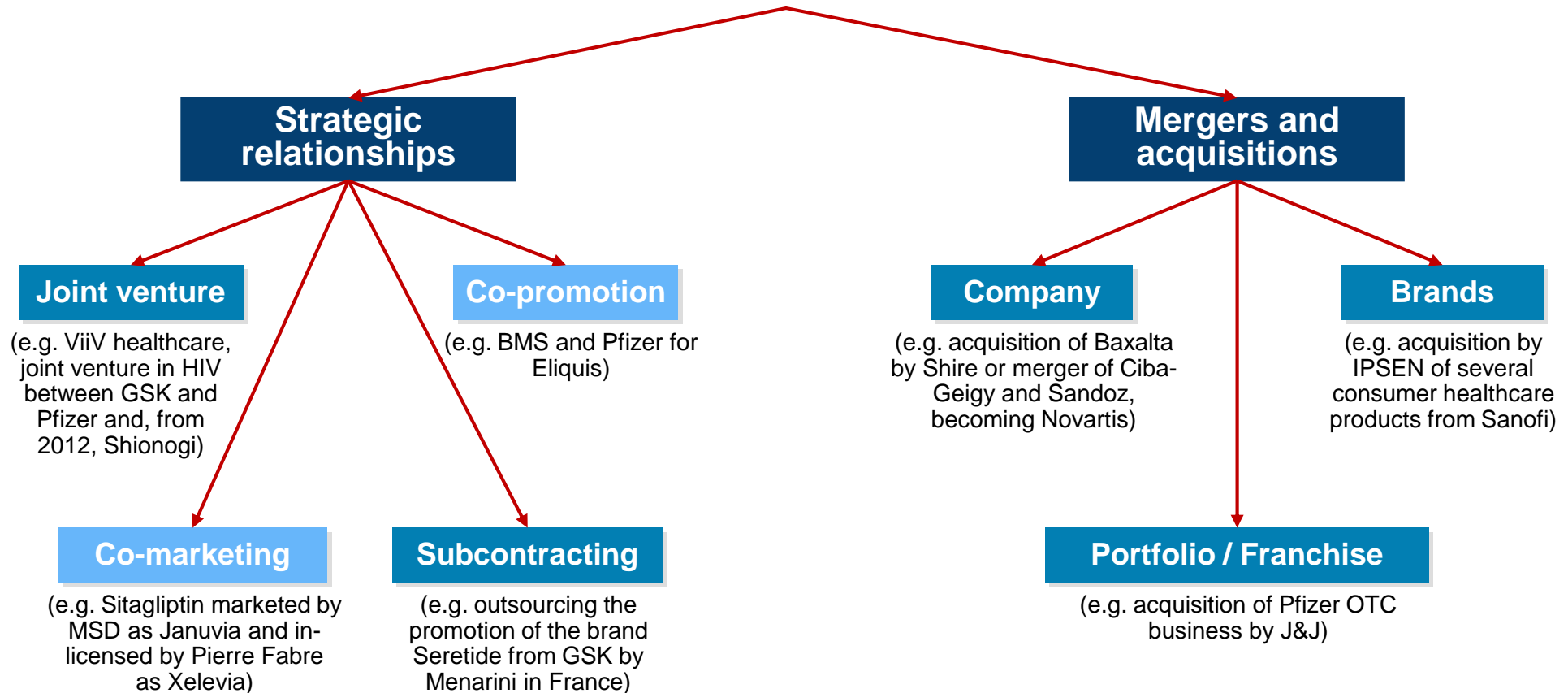
#### Mergers & Acquisitions

- Acquiring capabilities should be considered if desired capabilities can only be developed over long periods
- Integrating the acquiree's capabilities with the acquirer's ones involves major risks such as:
  - Culture clashes
  - Personality clashes
  - Incompatibility of management systemsresulting in degradation or destruction of the capabilities that were sought

**Note:** Capabilities can grow internally by systematizing their replication through the formulation and the implementation of SOPs<sup>2</sup>

**Co-promotion and co-marketing are the most common forms of business development deals in the pharmaceutical sector**

**Typology of BD&L deals**



Sources: Adapted by Smart Pharma Consulting from R. Grant 2008 and D. Waters 2006



The most important difficulty with co-promotion is to ensure an efficient collaboration between the two partners and a sufficient call pressure per physician

### Pros and Cons of co-marketing and co-promotion agreements

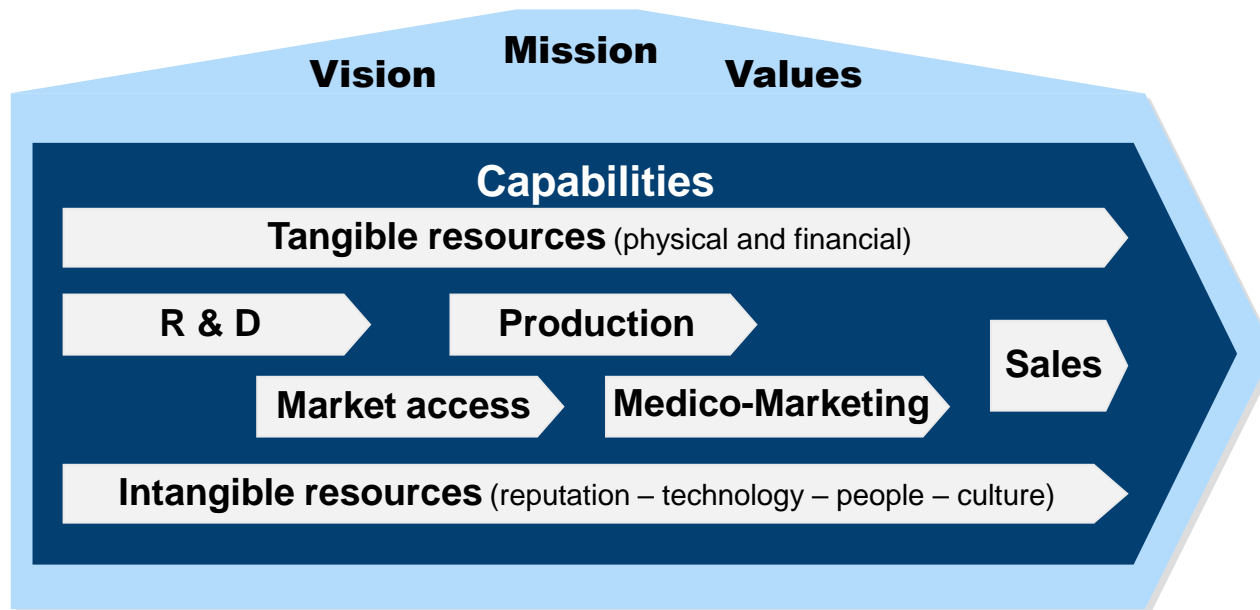
	Co-marketing	Co-promotion
Pros	<ul style="list-style-type: none"> <li>▪ Quick and easy to implement</li> <li>▪ No shared decision-making</li> <li>▪ Increased sales opportunities for the molecule which is promoted by two companies through a dual branding</li> <li>▪ Possibilities to book sales</li> </ul>	<ul style="list-style-type: none"> <li>▪ Higher recognition as a result of resource concentration</li> <li>▪ Cost-sharing with co-promoter</li> <li>▪ Unique product positioning</li> <li>▪ Leverage of partner's reputation</li> </ul>
Cons	<ul style="list-style-type: none"> <li>▪ Higher promotional spending (absence of shared costs)</li> <li>▪ Competition between co-marketers (cannibalization)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Difficulty in ascertaining sales credits and reward criteria</li> <li>▪ Increased management complexity</li> <li>▪ Increasing number of physicians limiting call pressure per brand per annum</li> </ul>

Sources: Smart Pharma Consulting analysis

# Business opportunity assessment requires to analyze attractiveness / key success factors by strategic segment and corresponding competitive advantage

## Methodology to assess business opportunities

### Business model



### Strengths & Weaknesses (Competitive advantage)

### Strategic segments (e.g. Rx-bound brands, generics, OTCs, devices, etc.)



### Opportunities & Threats (Attractiveness & Key success factors)

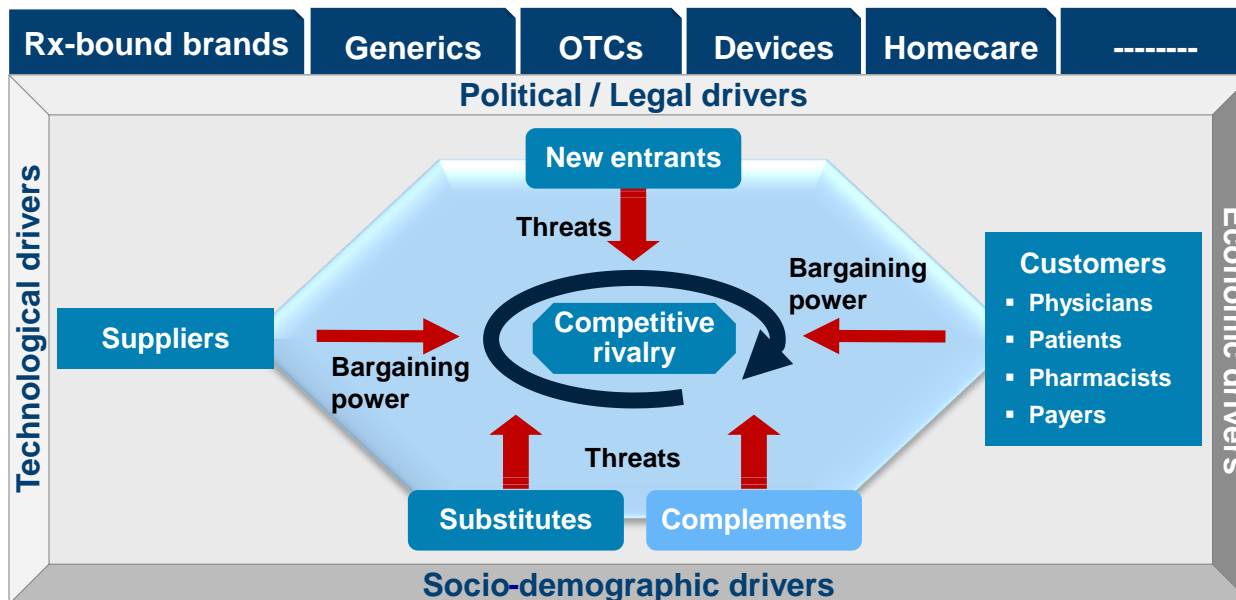
### Ambition & Strategic priorities

Sources: Adapted by Smart Pharma Consulting from C. Kim et al. and from D.J. Collis, HBR April 2008

<sup>1</sup> Political / legal, economic, socio-demographic and technological factors –  
<sup>2</sup> Including suppliers, new entrants, substitutes, complements

**Business opportunities by strategic segment, such as Rx-bound brands, generics, OTCs, etc. can be assessed through PEST analysis and the “5+1 forces framework”**

**Attractiveness of strategic segments (1/3)**



- The four key macro-environmental drivers:
  - Political / Legal
  - Economy
  - Socio-demography
  - Technology
- The five key micro-environment drivers:
  - Suppliers
  - Customers
  - New entrants
  - Substitutes
  - Competitive rivalry
- ... plus the “Complements” influence the attractiveness of each strategic segment and impact the success or the failure of pharma companies strategy
- These key drivers for change can be used to construct scenarios of possible futures, especially by adopting the “what if” technique

Analysis of Political / Legal – Economic – Socio-demographic – Technological drivers, called PEST analysis, and then the “5+1 forces Framework” after M. Porter will help pharma companies set an appropriate strategy per strategic segment

■ “Porter’s five forces”    ■ “Additional force”

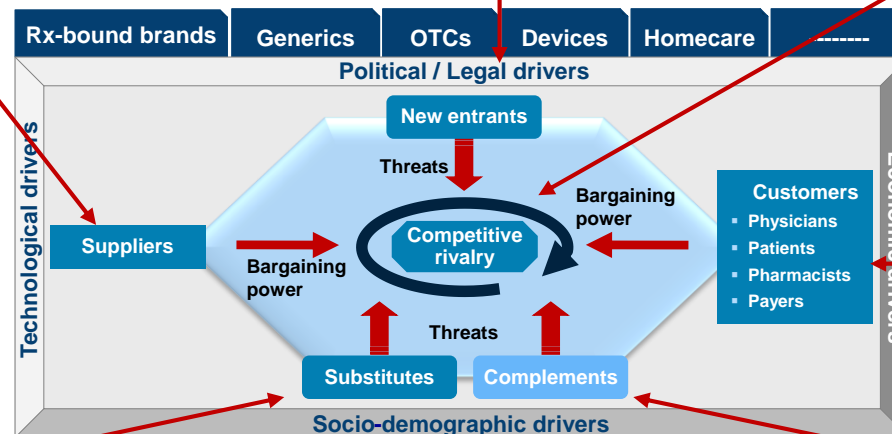
The “5+1 forces framework” is particularly helpful to identify the key stakeholders that will influence the long-term structure and profitability of strategic segments

### Attractiveness of strategic segments (2/3)

- **Most R&D-based pharma companies** being vertically integrated, threats from suppliers are rarely an issue
- **However, on the generics segment**, API<sup>1</sup> or DDS<sup>2</sup> suppliers may have a stronger bargaining power

- **New entrants** (e.g. innovative products, “me-too” products, generic products) are likely to modify competitive intensity and therefore pharma companies performance

- **Competitive rivalry intensifies with:**
  - Price discounting
  - New formulations, indications, products
  - Commoditization
  - Service improvement
  - Promotional costs



- **Higher pressure from groups of customers:**
  - Patient advocacy groups asking for better services
  - Buying groups have increased the distributors' leverage

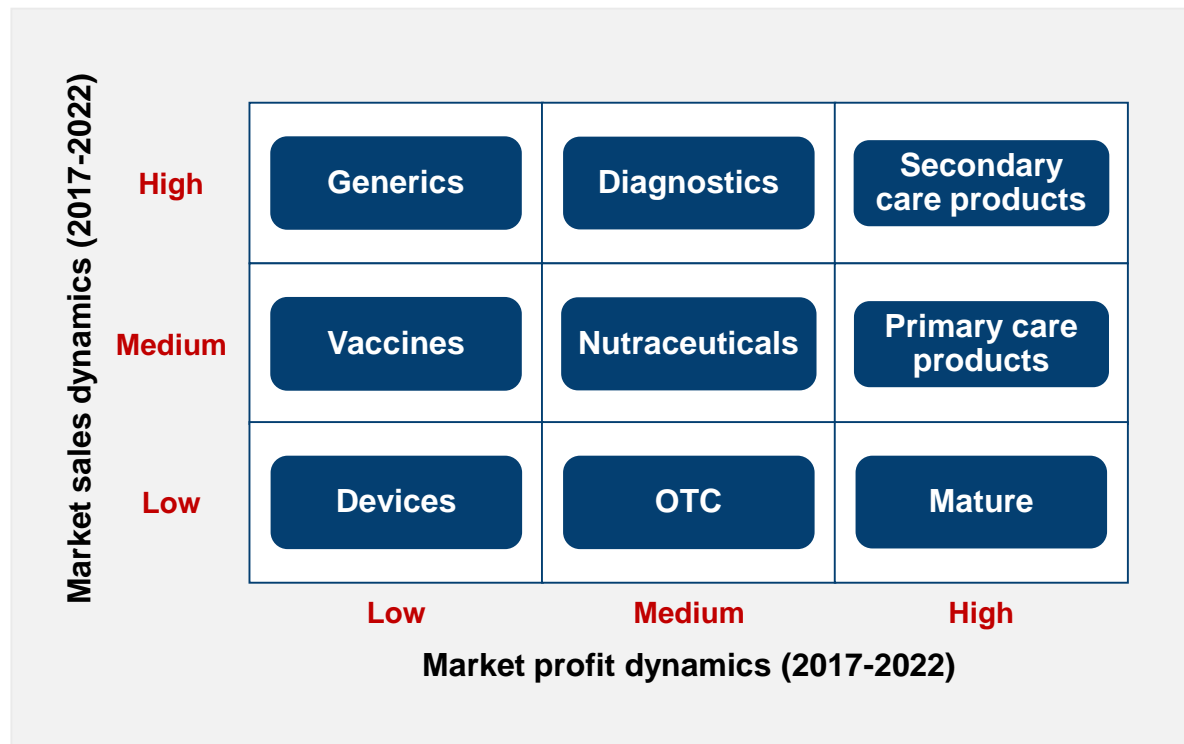
- **Substitute products or services include:**
  - Alternative therapies
  - Preventive therapies (e.g. vaccination vs. anti-infective drugs)

The “5+1forces framework” allows to determine how strategic segment’s profit will be shared between stakeholders, depending on their respective competitive advantage

- **Complementary products or services include:**
  - Devices (e.g. BGM<sup>3</sup>)
  - Diet food
  - Patient compliance management services

Attractiveness of new strategic segments should be put into a dynamic perspective and potential synergies with existing businesses also be considered

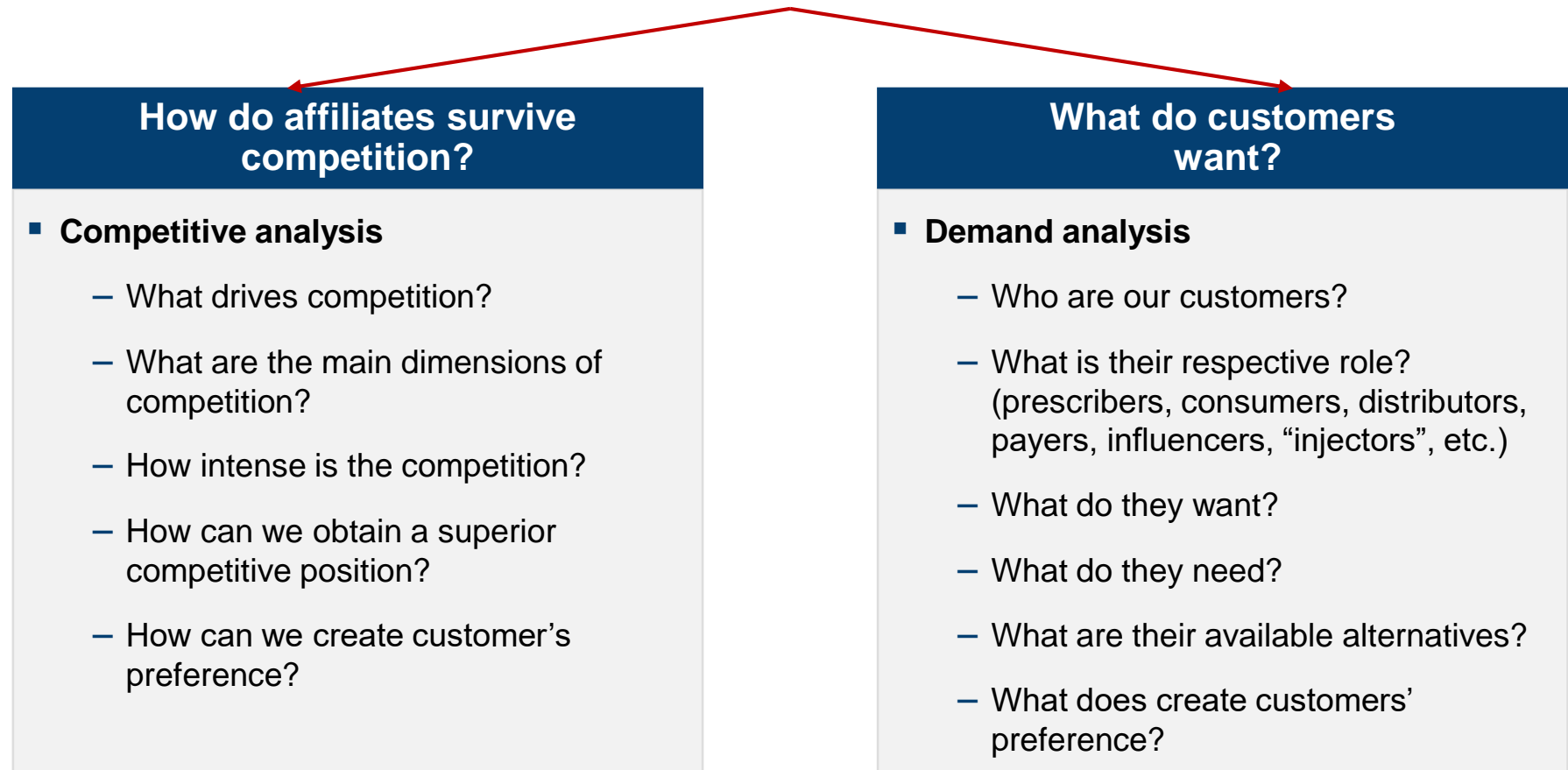
### Attractiveness of strategic segments (3/3)



- The attractiveness of a strategic segment should be defined, based on the evolution of economic indicators such as sales and profits
- Additional parameters such as potential synergies with the existing business should also be considered, while evaluating attractiveness of new strategic segments

**Key success factors by strategic segment where business opportunities have been identified are driven from competitive intensity and from customers wants**

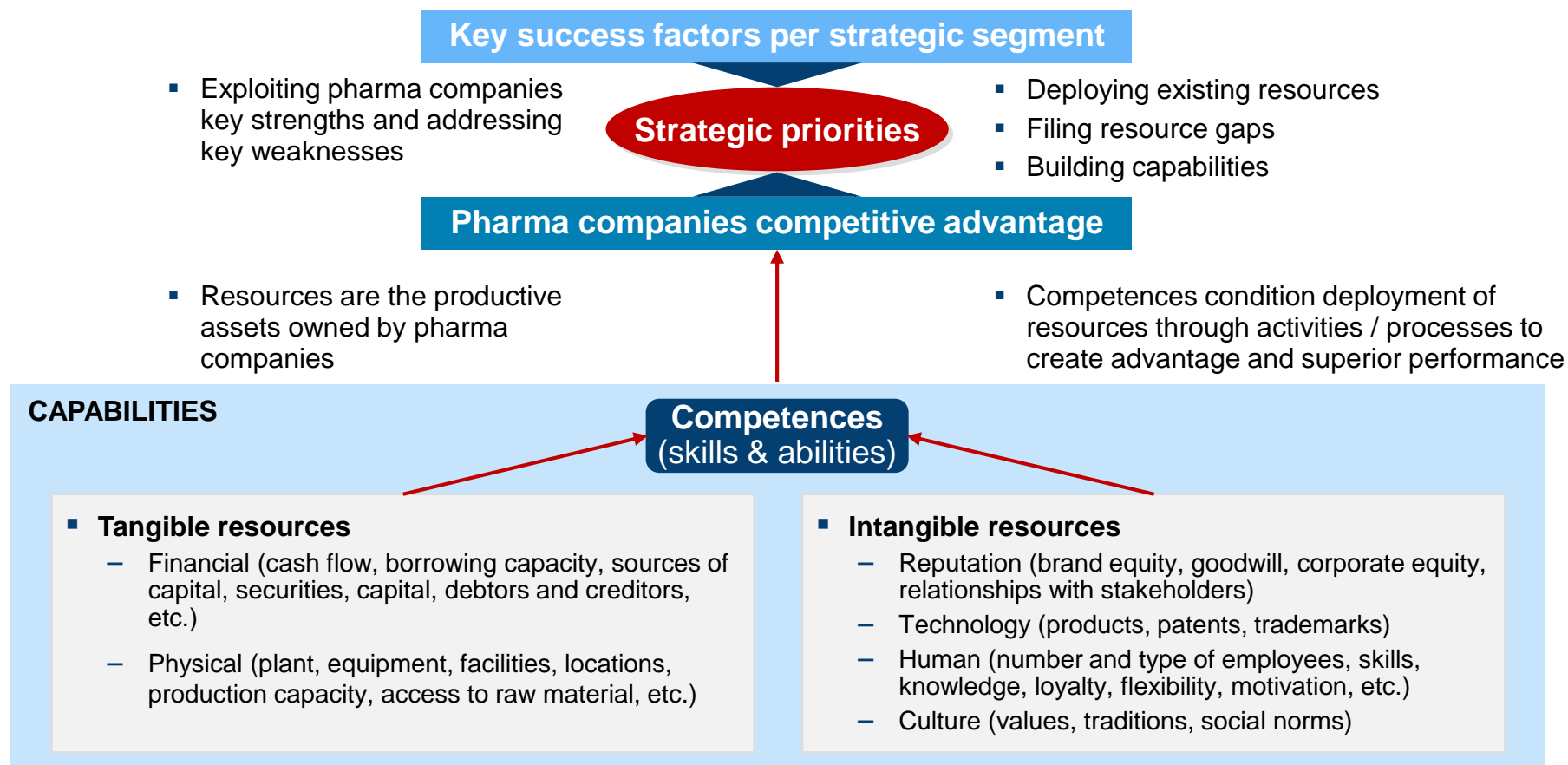
**Key success factors by strategic segment**



Sources: Adapted by Smart Pharma Consulting from R. Grant 2008

**Strategic priorities should be set after capabilities assessment to outperform competitors on key success factors inherent to each targeted strategic segment**

**Affiliate's competitive advantage and strategic priorities**



Sources: Adapted by Smart Pharma Consulting from R. Grant 2008 and D. Waters 2006

The “Advanced SWOT” is particularly appropriate to help pharma companies assess its potential competitive advantage per strategic segment and the possible synergies

**Advanced SWOT analysis**

**Environment assessment**

**Opportunities**

What environmental changes in targeted strategic segments may favor / hinder affiliate’s performance?

- **Macro-environmental drivers** (PEST factors)
- **Competitive forces** (5+1 forces framework)
- ⇒ **Favorable / unfavorable impacts on stakeholders resulting from environmental changes**
- ⇒ **Growth / profit reservoirs**

**Threats**

**Affiliate assessment**

**Strengths**

What are the affiliate’s strategic resources and competences relative to its competitors?

- **Resources** (tangible and intangible)<sup>1</sup>
- **Competences** (skills and abilities) } **Capabilities**
- ⇒ **Advantages / disadvantages vs. competitors**
- ⇒ **Means to leverage growth / profit reservoirs**

**Weaknesses**

**Advanced SWOT**

Opportunities	Relative importance	Threats	Relative importance
Strengths	Relative importance	Weaknesses	Relative importance



Pharma companies' ambition and strategy to seize business opportunities in new strategic segments can be formalized with the following analytical tools

**Strategic options and strategic segment card**

**Strategic options**

Key success factors per strategic segment	Weighting	Affiliate's capabilities <sup>1</sup>						Affiliate's strategic options (strength to leverage or weakness to address)
		++	+	=	-	--		

Higher
 Lower

++ Major strength    + Minor strength    = Neutral  
 - Minor weakness    -- Major weakness

**Strategic segment card**

Ambition	
Qualitative	Quantitative
<b>Strategic option 1</b> 	<b>Strategic option 2</b> 
<b>Strategic option 3</b> 	<b>Strategic option 4</b> 
<b>Key actions</b> 	<b>Key actions</b> 
<b>Key actions</b> 	<b>Key actions</b> 

The evaluation of each business opportunity will be determined by its degree of suitability, acceptability and feasibility

### Evaluation of business development opportunities (1/2)

#### Suitability

- Does the business opportunity address the key issues related to the strategic position of the company?
- To what extent strategic options will:
  - Fit with key market drivers?
  - Leverage strategic capabilities?
  - Meet stakeholders expectations?

#### Tools

- **Ranking of strategic options** (based on Advanced SWOT analysis)
- **Decision trees** (evaluation of future opportunities by progressively eliminating others as additional requirement criteria are introduced into the evaluation)
- **Scenarios** (strategic options considered against possible future situations)

#### Acceptability

- Acceptability refers to the expected performance outcomes (e.g. return, risk) of a strategy
- To what extent do these outcomes meet the expectations of stakeholders?

#### Tools

- **Return:** expected benefit measurement:
  - Profitability (ROCE<sup>1</sup>, payback, DCF<sup>2</sup>)
  - Cost-benefit analysis
  - Real options analysis
  - Shareholder value analysis (SVA)
- **Risk:** probability and consequences of the failure of a strategy:
  - Financial ratio projections
  - Sensitivity analysis
- **Stakeholders reactions** (mapping)

#### Feasibility

- The feasibility is concerned with the capabilities of a company to implement a strategy that has been envisaged

#### Tools

- **Financial feasibility assessment** through a cash flow analysis (forecasting of the needed cash to deliver the strategy and identification of the likely sources to fund that cash)
- **Evaluation of capabilities needed:**
  - Gap analysis: available vs. required capabilities
  - Assessment of changes required
  - Determination of “if” and “how” to implement changes

## Discounted cash flows and sensitivity analysis are amongst the most frequently used techniques to assess business acceptability in the pharmaceutical sector

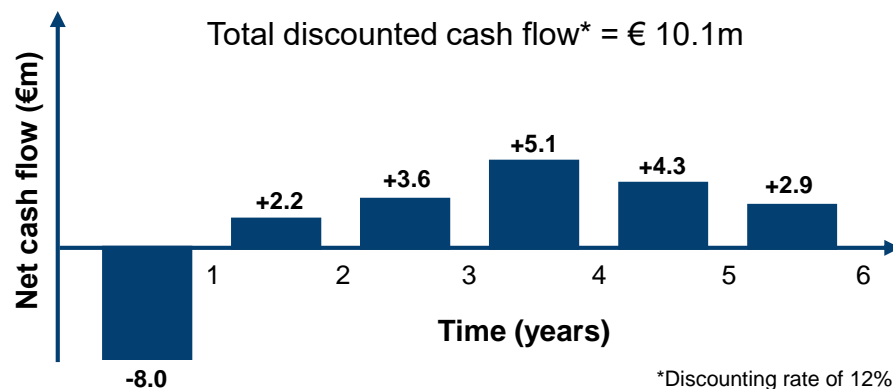
### Evaluation of business development opportunities (2/2)

#### Examples of acceptability criteria

*Illustrative*

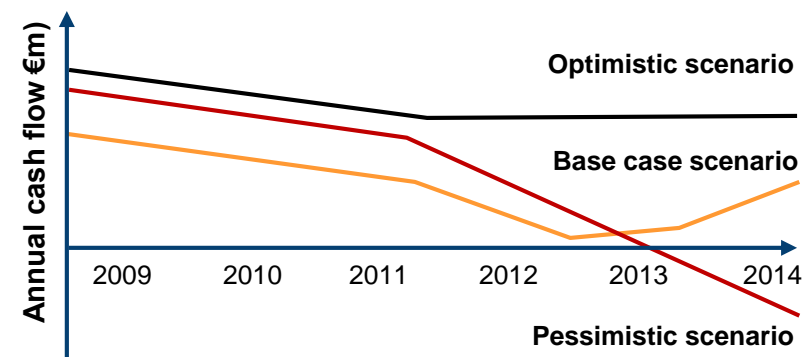
#### Return: Discounted cash flows (DCF)

- The DCF is an investment appraisal technique that can be used for business development opportunities (e.g. M&A, co-marketing, co-promotion, other strategic relationships)
- The total discounted cash flow or the net present value (NPV) is only as good as the assumptions on which it is based such as: sales forecasts, operating investment required, price changes, etc.



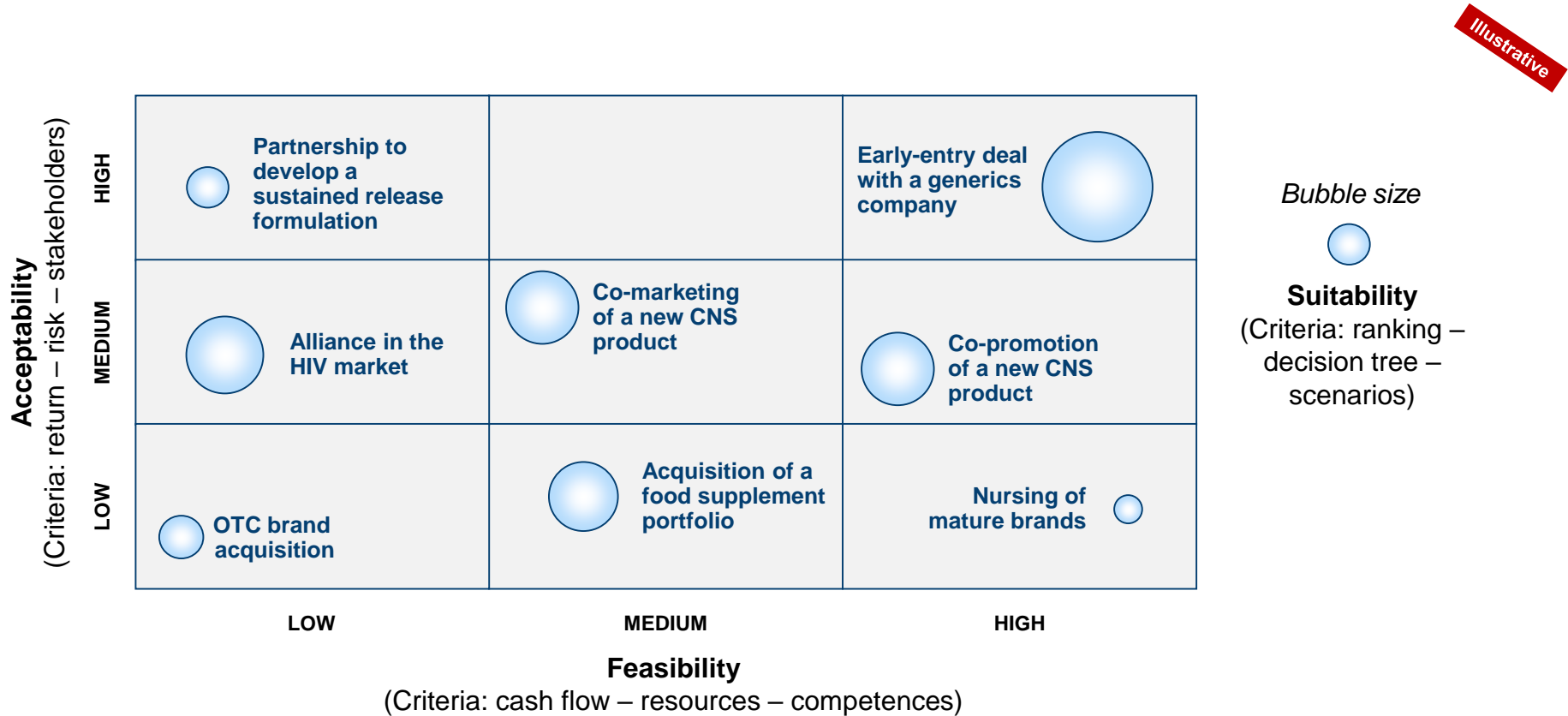
#### Risk: Sensitivity analysis

- Sensitivity or “what if” analysis is a useful technique for assessing the extent to which the success of a preferred business development opportunity is dependent on the key underlying assumptions, such as sales forecasts, price changes, investment requirements, new entrants, etc.
- This analysis helps estimate both the risk and the degree of confidence attached to an opportunity



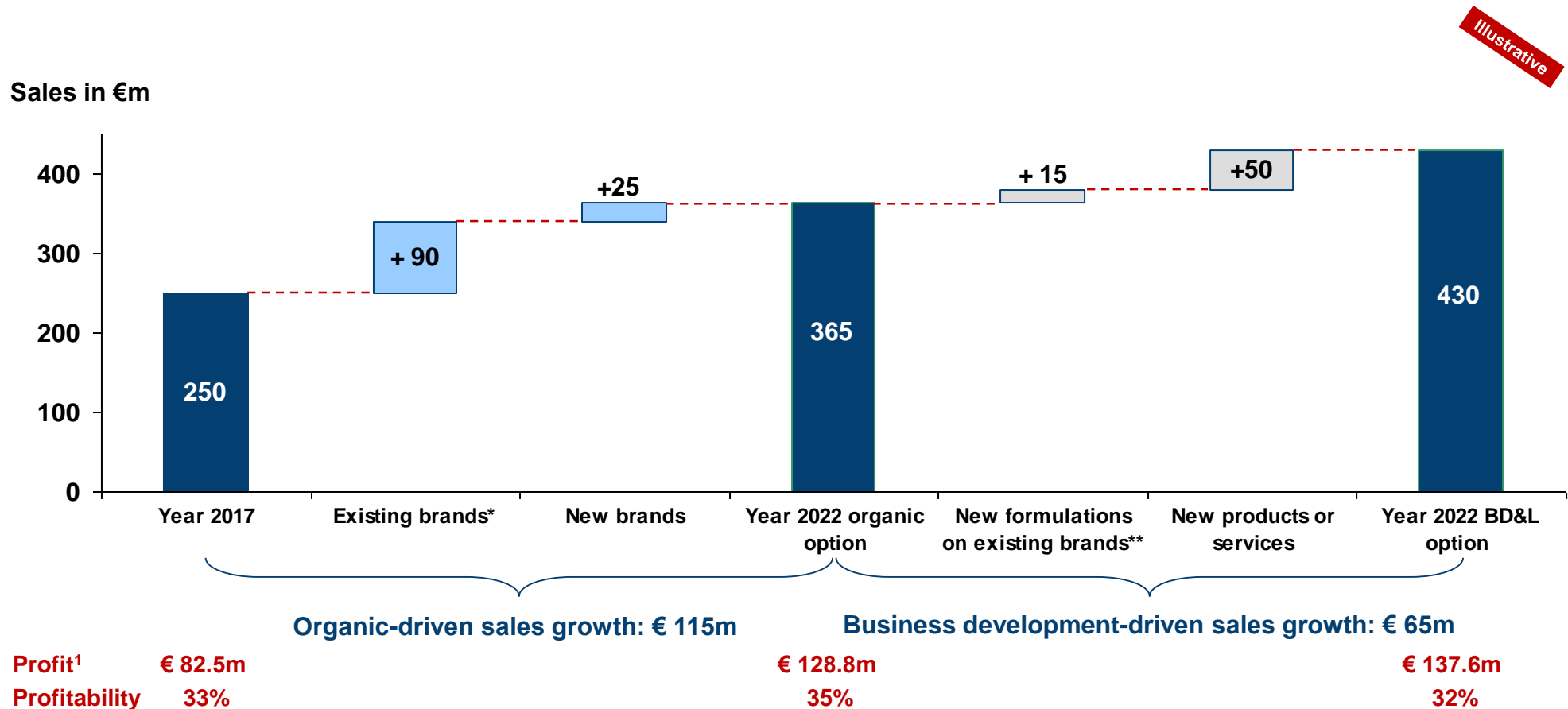
The strategic evaluation matrix represents a convenient means to put into perspective acceptability, feasibility and suitability of different business development projects

**Business development evaluation matrix**



In general, business development deals boost sales and profit growth, while altering profitability, due to profit sharing agreement and resulting organizational dysfunction

### Impact of business development initiatives

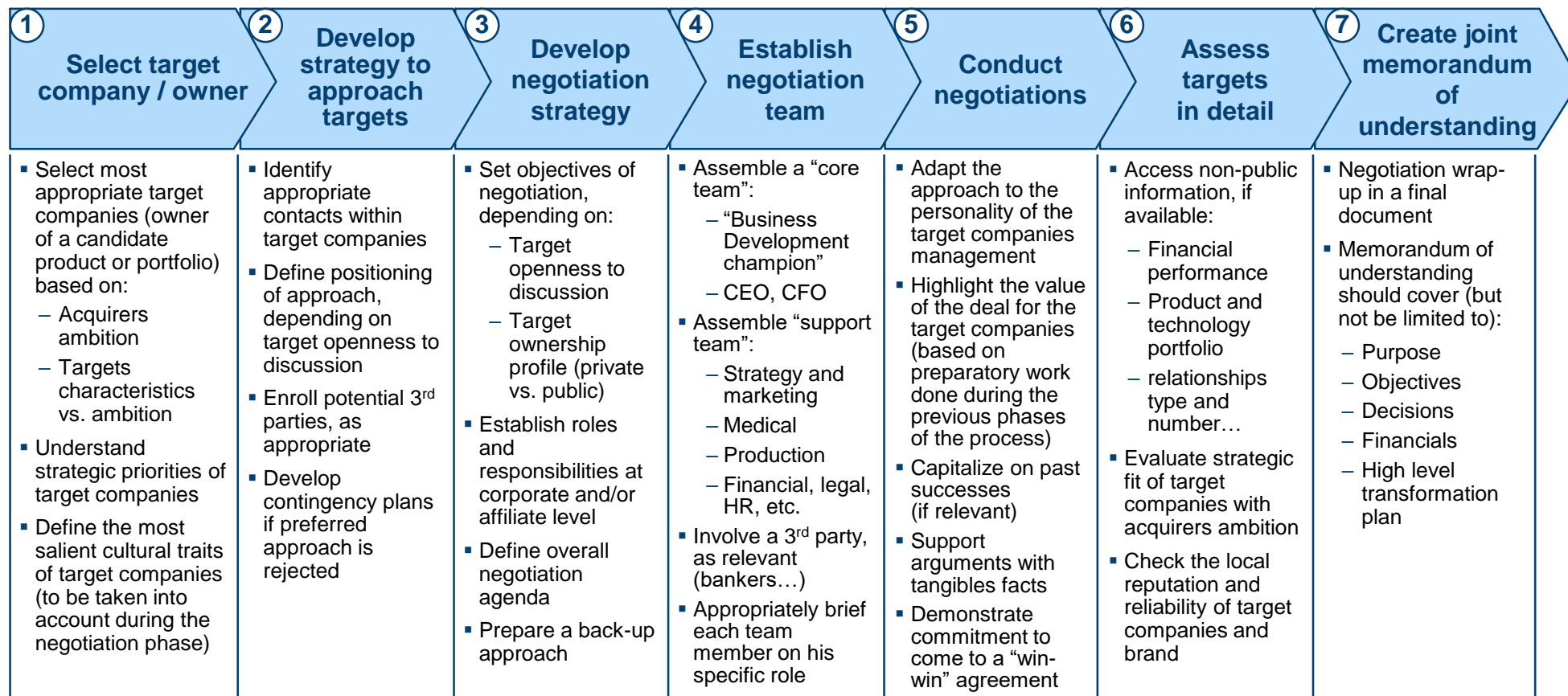


Sources: Smart Pharma Consulting analysis

\*Including new indications, dosages, formulations internally developed \*\* If externally developed – <sup>1</sup> EBIT: Earnings before interest and taxes

## Business developers should follow a well-defined process to approach target companies and raise their interest for strategic relationships or M&A opportunities

### Process to approach target companies

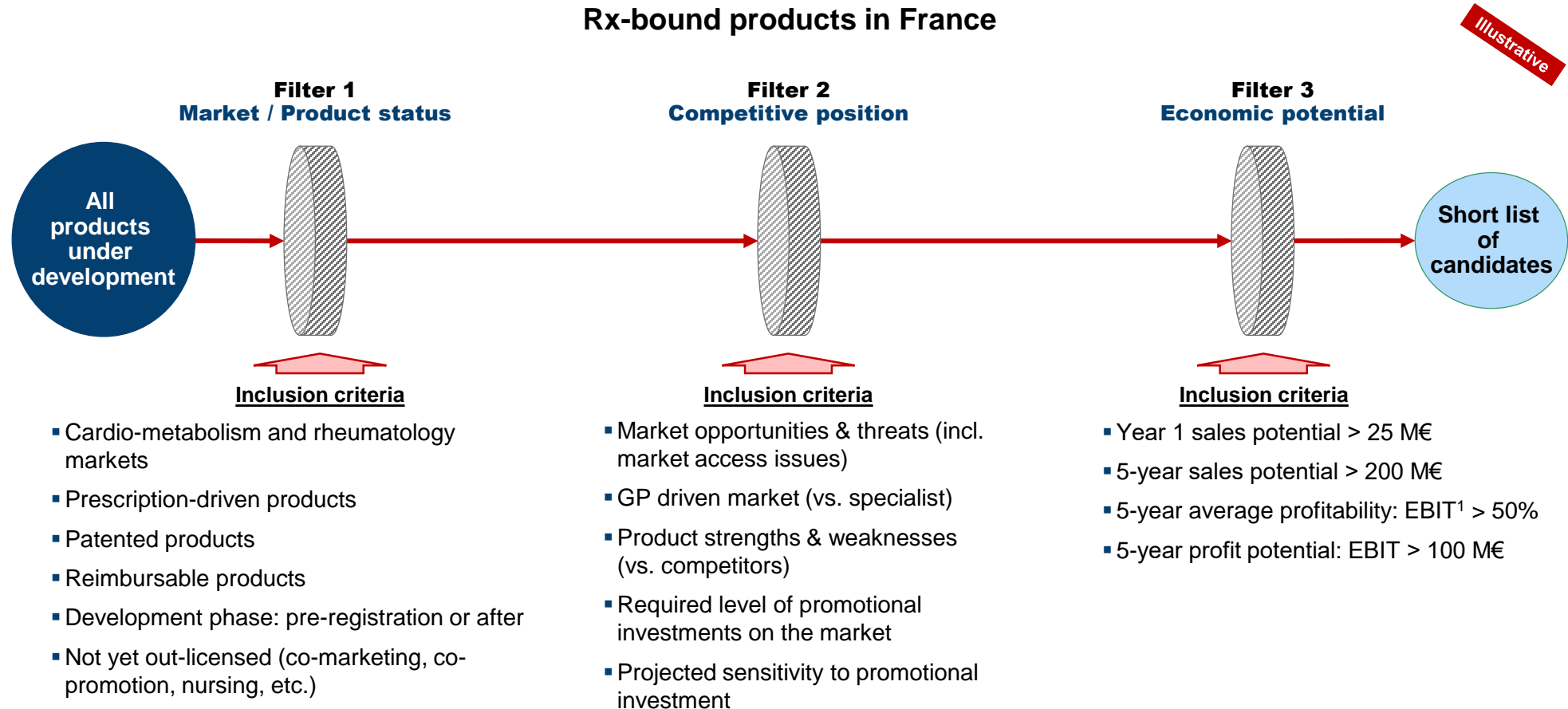


Sources: Smart Pharma Consulting analysis

The selection of most attractive candidate products under development, within a defined strategic segment, can be established through the following methodology

**Under-development product screening**

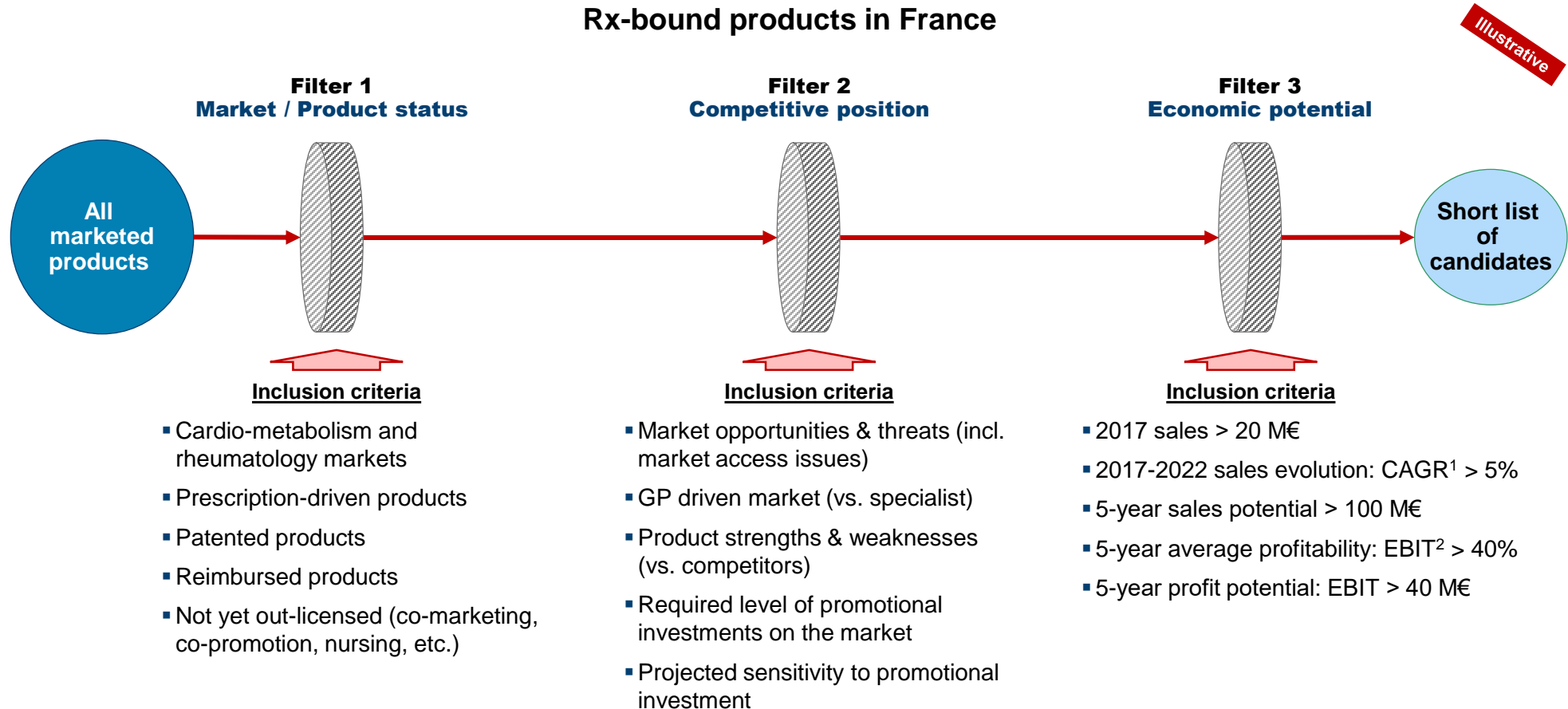
Rx-bound products in France



The selection of most attractive candidate products already marketed, within a defined strategic segment, can be established through the following methodology

### Marketed product screening

Rx-bound products in France





The results of the screening process, leading to the most attractive candidate products, can be summarized on simple charts to facilitate comparisons

### Example of short listed candidate products

#### Under development products

Molecule	Brand name	Originator	Licensing agreement	Mode of action	Indications	EU status
Vildagliptin	GALVUS	Novartis	No	DPP IV antagonist	• Type 2 diabetes	Registered (launched in UK)
Saxagliptin	ONGLYZA	BMS	AZ (worldwide) Otsuka (Japan)	DPP IV antagonist	• Type 2 diabetes	
Azimilide	STEDICOR	P&G US	Mitsubishi Tanabe - Asia	Potassium channel blocker	• Arrhythmia	
Lercanidipine + enalapril	ZANERIL ZANITEK	Recordati	Meda (G), Solvay (Austria)	ACEI+ CCB	• Hypertension	
Olmesartan amlodipine	-	Daiichi-Sankyo	TBD	ARAI+CCB	• Hypertension	
Tolvaptan	SMASKA	Otsuka	No	Vasopressin 2 antagonist	• Coronary failure	
Aliskiren	RASILEZ	Novartis	No	Renin inhibitor	• Hypertension	
Prednisone CR	LODOTRA	Nitec & SkyePharma	Merck-Serono	Immuno-depressant	• Rheumatoid arthritis	
Golimumab	-	Centocor (J&J)	Schering Plough (excl. US)	Anti-TNF alpha	• Spondylarthritis • Psoriasis • Rheumatoid arthritis	

#### Marketed products

Molecule	Brand name	Originator	Therapeutic class	Sales 2017	CAGR 2017-2022 <sup>1</sup>	Sales 2017-22	Promotional spend (2017)	Profits 2017-22
Rosuvastatin	CRESTOR	Astra Zeneca	C10A1	162 M€	25%	162 M€	20 M€	142 M€
Pravastatin + aspirin	PRAVADUAL	BMS	C10A1	21 M€	30%	21 M€	5 M€	16 M€
Ezetimibe	EZETROL	Merck&Co	C10A9	75 M€	12%	75 M€	7 M€	68 M€
Ibandronic acid	BONVIVA	Roche	M05B3	32 M€	15%	32 M€	16 M€	16 M€
Eletriptan	RELPAK	Pfizer	N02C1	26 M€	4%	26 M€	6 M€	20 M€
Hydroxyzine	ATARAX	UCB Pharma	N05C	20 M€	2%	20 M€	4 M€	16 M€
Mometasone furoate	NASONEX	Schering Plough	R01A1	42 M€	5%	42 M€	9 M€	33 M€
Montelukast	SINGULAR	Merck&Co	R03J2	101M€	4%	101 M€	9 M€	92 M€
Levocetirizine	XYZALL	UCB Pharma	R06A	36 M€	-5%	36 M€	11 M€	25 M€

Illustrative

“ID” cards collecting key facts, figures and analyses related to each candidate product are particularly useful before approaching their respective owner

### Example of identity card for short-listed candidate products

Molecule:-----

Brand name: -----


Originator: -----

Therapeutic class: -----

#### Product attributes

<b>Sales 2017</b>	<b>CAGR<sup>1</sup> 12-17</b>	<b>Sales 12-17</b>	<b>Promo spend<sup>2</sup></b>	<b>Profits 12-17</b>
-----M€	-----%	-----M€	-----%	-----M€

<b>Indications</b>	<b>Side effects</b>	<b>Status</b>
1.	1.	▪ Patent expiry date: -----
2.	2.	▪ Reimbursement level: -----%
3.	3.	▪ Price: a:----- b:-----
		▪ Promotional sensitivity: 

#### SWOT analysis

<b>Market Opportunities</b> <div> <div>-----</div> <div>-----</div> <div>-----</div> </div>   	<b>Market threats</b> <div> <div>-----</div> <div>-----</div> <div>-----</div> </div>   
<b>Product strengths</b> <div> <div>-----</div> <div>-----</div> <div>-----</div> </div>   	<b>Product weaknesses</b> <div> <div>-----</div> <div>-----</div> <div>-----</div> </div>   

#### Value for the acquirer

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#### Value for the owner

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#### Recommendations

☒ **GO**

☐ **NO GO**

#### Preferred types of deals

☒ Exclusive marketing license
 ☒ Co-marketing
 ☐ Co-promotion

☐ Non exclusive marketing license
 ☐ Nursing
 ☐ Acquisition

☐ Other:-----

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**BD&L opportunities may play a key role in improving pharma companies overall performance (top and bottom lines) while mitigating their business risk**

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**Key learnings (1/2)**

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- BD&L refers to **strategic relationships** or **merger & acquisition** deals which enable pharma companies to strengthen their competitive position
- BD&L initiatives are expected to **generate extra revenues**, **increase profits** and/or **spread business risk**, while **leveraging potential synergies**
- **Synergies** result from a better **mixing** and **matching of capabilities**, and are the greatest when opportunities are in businesses similar to that in which pharma companies operate
- **Strategic relationships** and **M&A** may contribute to **build capabilities** and **create** business **synergies**, but not without **difficulties** and risks
- **Co-promotion** and **co-marketing** are the **most common forms** of business development **deals** in the pharmaceutical sector, especially at affiliate level
- Business opportunity **assessment** requires to analyze **attractiveness / key success factors** by strategic segment and pharma companies corresponding **competitive advantage**
- **Business opportunities** by strategic segment, such as Rx-bound brands, generics, OTCs, etc., can **be assessed** through **PEST analysis** and the **“5+1 forces framework”**

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**Business opportunities should be carefully assessed through strategic analyses and with specific processes and tools to maximize the chances of success**

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**Key learnings (2/2)**

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- The “**5+1 forces framework**” is particularly helpful to **identify** the **key stakeholders** that will **influence the long-term structure** and **profitability** of strategic segments
- **Attractiveness** of new strategic segments should be put into a **dynamic perspective** and **potential synergies** with pharma companies existing businesses should also **be considered**
- The proposed “**Advanced SWOT**” is particularly appropriate to help pharma companies **assess** their potential **competitive advantage** per strategic segment and **possible synergies**
- The **evaluation** of each business opportunity will be determined by its degree of **suitability**, **acceptability** and **feasibility**
- **Discounted cash flows** and **sensitivity analysis** are amongst the most frequently used techniques **to assess business acceptability** in the pharmaceutical sector
- In general, BD&L **deals boost sales** and **profit growth** while **altering profitability**, due to profit sharing agreements and organizational dysfunctions
- **Business developers** should **follow** a well-defined **process to approach target companies** and raise their interest for strategic relationships or M&A opportunities

## Smart Pharma Consulting has helped pharma companies and private equity companies assess business opportunities in various therapeutic areas

### Experience & competencies in BD&L and Strategic Due Diligences

- **Smart Pharma Consulting** has carried out several **BD&L** and **Strategic Due Diligence** projects for big and mid-sized pharma companies or for private equity firms:
  - **Pharmaceutical companies** such as:  
ALK – Amgen – Chiesi – Esteve – Ethypharm (CMO/Drug delivery company) – IPSEN – NextPharma (CMO) – Nordic Pharma – Polymedic (CMO) – Pierre Fabre – Roche – Schering-Plough – Servier – Synerlab (CMO) – Schwabe – UCB Pharma
  - **Private equity firms** such as:  
Alma Capital – Astorg – Cinven – Exane – Keensight Capital – PAI – Rothschild – Sagard – Weinberg
  - In **various geographic areas**:  
Western and Eastern Europe – USA – Latin America – Middle East – Africa
  - For **innovative** and **generic products** belonging to many **different therapeutic areas** such as:  
Oncology – Immunology – Ophthalmology – Allergy – Cardiology – Endocrinology & Diabetes – Pulmonology. etc.

## Smart Pharma Consulting has carried out several business development projects & Strategic Due Diligences on numerous international markets

### Examples of Business Development Projects & Strategic Due Diligences

- 2017** Value assessment of a new respiratory product in a co-promotion perspective
- 2017** Search of a worldwide pharma partner to market a dermatological product range
- 2016** Screening of target companies involved in the OTC business
- 2015** Evaluation of a “therapeutic” vaccine in HIV on EU5 and US markets
- 2015** Value assessment of a new product in osteoporosis in EU5 markets
- 2015** Preparation of a value dossier for “super-generics” and screening of mid pharma companies for licensing-in agreements
- 2015** Opportunity assessment of products to be acquired or in-licensed at the European level
- 2014** Evaluation of an existing brand in lipodystrophy
- 2014** Evaluation of the potential of a new treatment for psoriasis in the five largest European markets
- 2014** Evaluation of the potential of a new treatment for severe osteoporosis in seven European markets
- 2013** Identification of primary care developing and existing product candidates for the French market
- 2012** Identification of hospital and secondary care developing and existing product candidates for the French market
- 2010** Estimate of the sales potential of an oncology portfolio in: Iran, Iraq, Belorussia and Kazakhstan
- 2008** 10-year sales forecasts for a leading anti-diabetic drug in ten countries, including the USA
- 2007** Sales potential estimate for an ophthalmology franchise in four major European countries
- 2007** Sales potential estimates for a biosimilar in six European countries
- 2007** 5-year sales forecasts for a range of products in endocrinology in eight European countries
- 2006** Strategic Due Diligence estimating the potential of a 10-product portfolio in Spain, USA, France and UK

Sources: Smart Pharma Consulting analyses

## The Smart Pharma Publications

- Our publications have in common to:
  - Be well-documented and propose in-depth analyses
  - Share innovative concepts, methods and tools

## The Best of Smart Pharma 2017

- This e-book is the “best-of” our 2017 publications which have been dedicated to the development of executives
- Thus, we have published:
  - 2 Business reports:
    - The French healthcare system and pharma market
    - The French generics and biosimilar markets
  - 2 position papers in the “Smart Manager Series”:
    - Be a Smart Manager, not just a good one
    - Time optimization
  - 5 position papers in the “Best-in-Class Series”:
    - MSLs
    - Pharma Marketers
    - Medical Reps
    - Hospital KAMs
    - Pharma BD&L

## 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 pharma business issues
  - >60 position papers incl. Concepts, Methods and Tools

Best regards,

Jean-Michel Peny