

Smart Pharma 2019

Half-year Collection

Concepts

Methods

Tools



Smart Pharma
Consulting

Market Insights & Strategy

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

Management

- Hospital & Institution Relationships in Regions
- Strategic KOL Engagement Planning
- Excellence in Execution
- Storytelling in Business

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

Key features

- For the past 18 years, **becoming Smarter** has been our **corporate ambition**...
- ... and **providing our clients with Smarter services** has been our **corporate mission**
- Smart Pharma Consulting has strived to allocate its resources and to develop its capabilities to:
 1. **Generate** and **disseminate high quality insights** regarding healthcare environment and pharmaceutical market
 2. **Share knowledge** and **thoughts** through **consulting**, **training** and **teaching activities**, as well as through **numerous publications** such as reports, books, articles, position papers
 3. **Offer innovative viewpoints, concepts, methods, tools** and **solutions** that **outperform mainstream ones**

Our triple expertise provides us with a unique positioning on the consulting market and enables us to create synergies to deliver our clients smarter services

Smart Pharma Consulting unique positioning



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 website¹, illustrates our “innovative power”

Smart Pharma Consulting innovations

	Concepts / Methods	Tools	Opinions
Strategy & Management	<ul style="list-style-type: none"> 4Ws (What, Why, so What, What to do?) Preference-driven Strategy Pharma Corporate Reputation The Smart Manager 	<ul style="list-style-type: none"> Development Strategy Matrix Corporate ID Card Advanced SWOT Customer Preference Card Pharma Reputation Index 	<ul style="list-style-type: none"> <i>The mirage of the BRICs²</i>
Marketing & Sales	<ul style="list-style-type: none"> 4Ws Brand Booster Program Segmentation KAM Expert Wheel The ELITE Program 	<ul style="list-style-type: none"> Brand Preference Mix Index Behavioral Prescriber Segmentation (BPS) KEIs³ vs. KPIs⁴ Portfolio Strategic Matrix High Impact Interactions (H2I) 	<ul style="list-style-type: none"> <i>Brand preference supersedes brand satisfaction</i> <i>Med reps are key to drive physician preference</i>
Medical	<ul style="list-style-type: none"> 4Ws 	<ul style="list-style-type: none"> KOL ID Card KOL Partnership Plan (K2P) Integrated Regional Strategic Plan 	<ul style="list-style-type: none"> NA

Sources: Smart Pharma Consulting analysis

¹ www.smart-pharma.com – ² Brazil, Russia, India, China –

³ Key execution indicators – ⁴ Key performance indicators

Pharma Market Insight Studies

**Methods
&
Tools**



**Smart Pharma
Consulting**

Smart Pharma Expertise

Competitive landscape

Health authorities – Clients – Competitors

Brand position

Performance – Resources – Development

Brand objective

Sales & Profit forecasting

Brand strategy

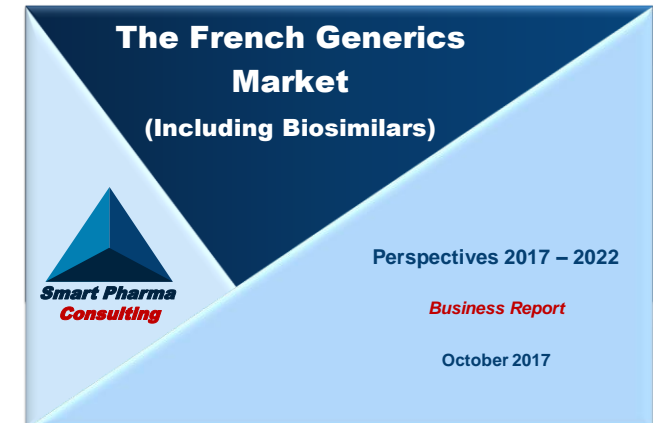
Positioning – Segmentation – Targeting

Brand tactics

Sales force effectiveness

Smart Pharma Consulting is well-known for the quality of its market insight studies, offering well-documented insights and thoughtful analysis to make better decisions

Examples of market insight studies recently published

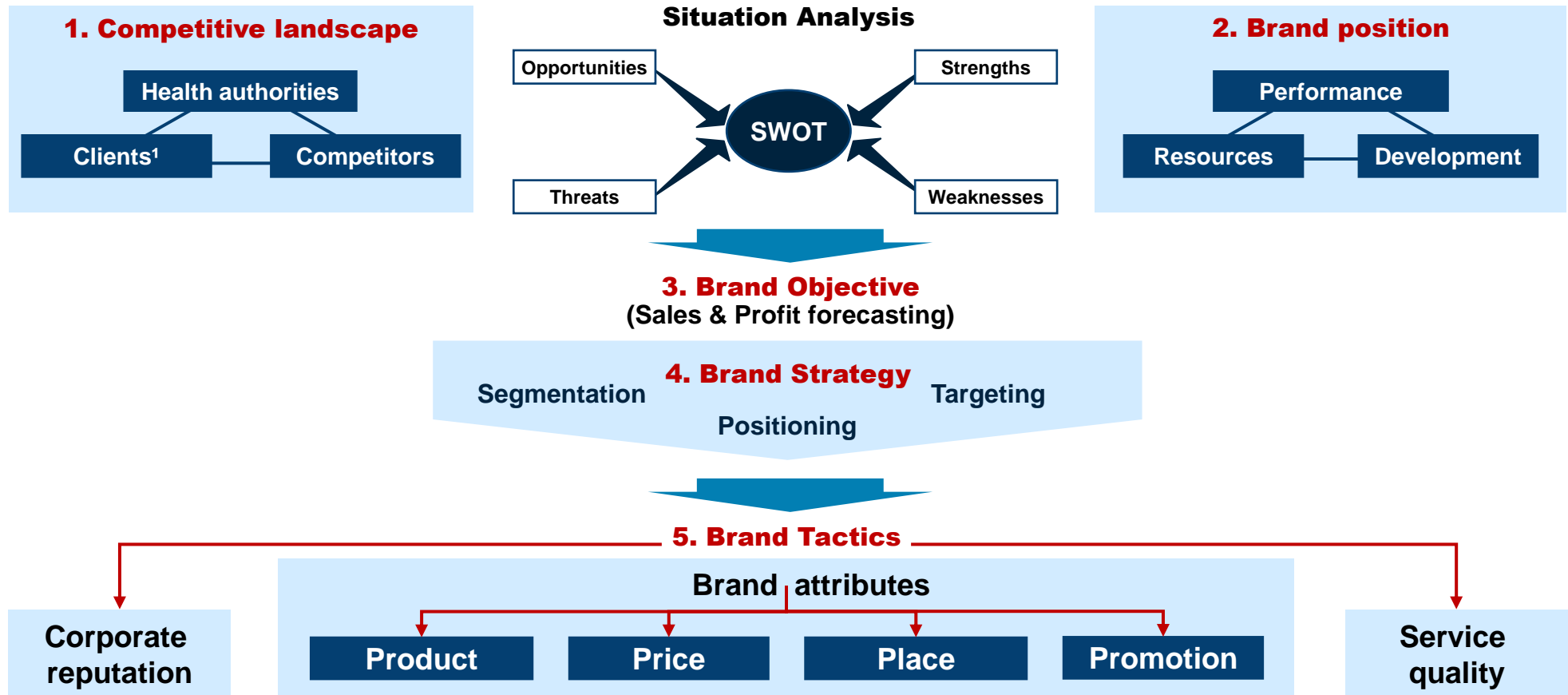


Smart Pharma Consulting

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

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

Marketing thinking process



Our ability to collect insights from all market stakeholders and our robust analytical skills allow us to deliver high value-added recommendations

Methodological approach

Clients

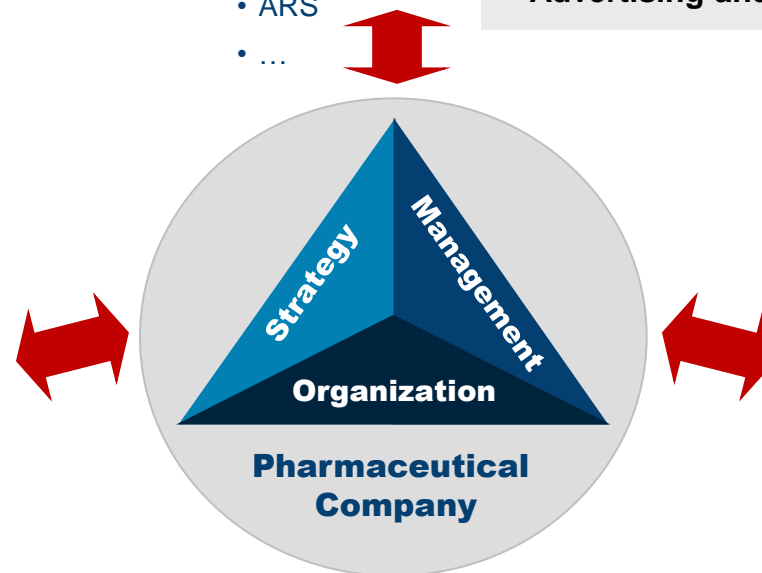
- Physicians
- Pharmacists
- Patients
- Hospitals
- Distributors
- Payers
- Learned societies
- Unions
- ...

- Therapeutic needs
- Prescription patterns
- Preference drivers
- Delivery standards
- Purchasing habits

Health authorities

- EMA
- FDA
- ANSM
- CEPS
- HAS
- ARS
- ...

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



Competitors

- Innovators
- Generic companies
- Biotech companies
- OTC companies
- ...

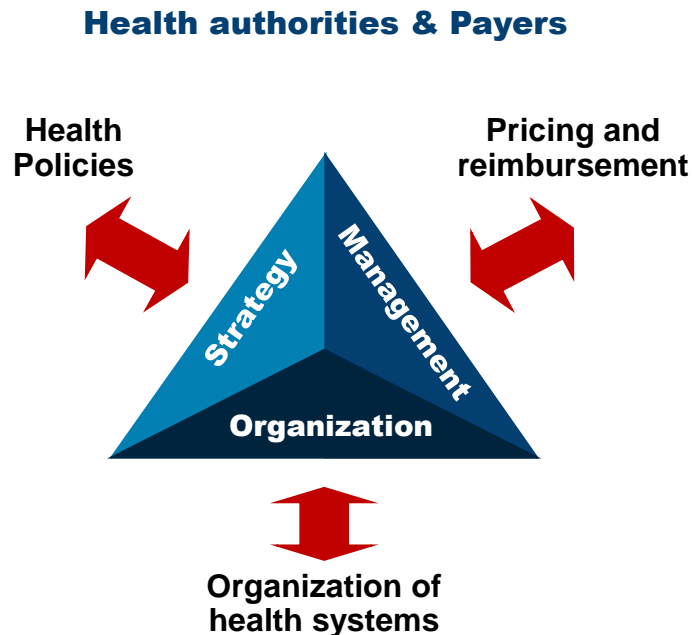
- Benchmarking
- Differentiating factors
- Growth drivers / orientations

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

Health authorities

Market studies targeted at health authorities

Illustration



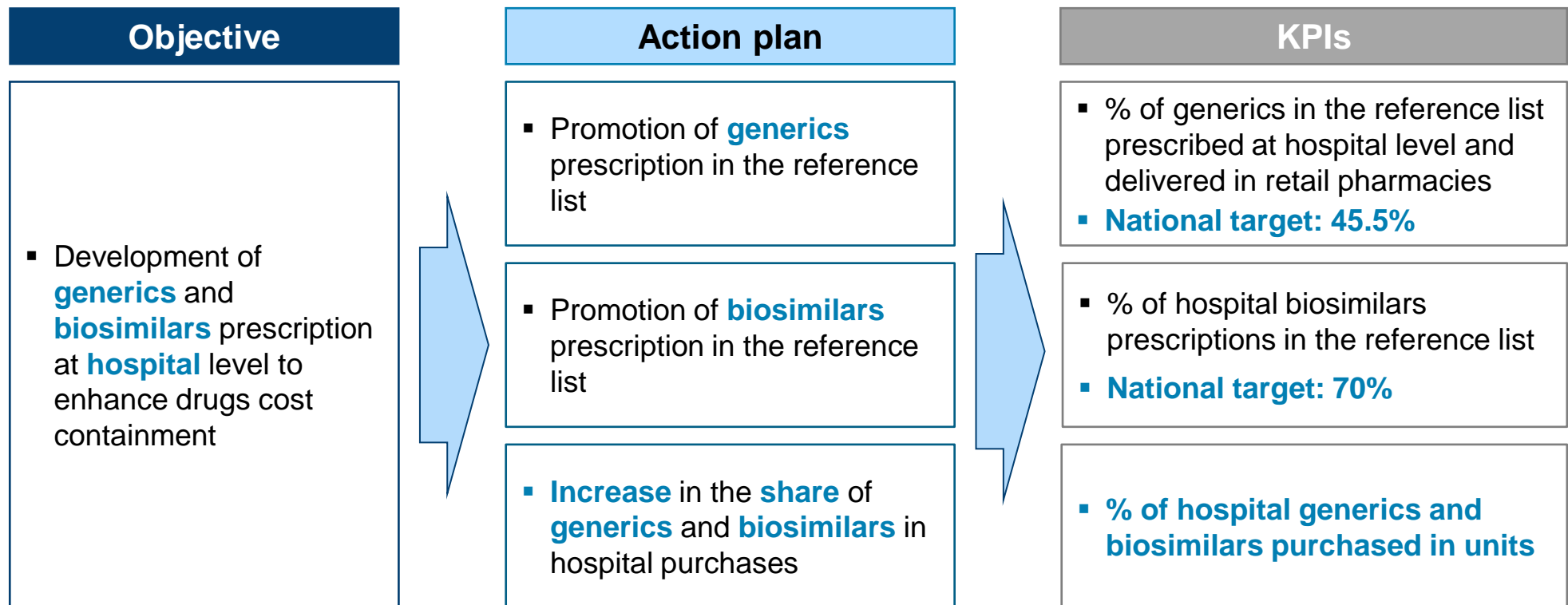
Types of studies recently undertaken

- **Organization of health systems**
 - Research on health systems across the world
 - Market access systems by country
 - Study of the organization, the composition and the strategic priorities of regional health bodies
- **Health Policies**
 - Analysis of healthcare reforms across Europe
 - Study of healthcare expenditure containment policies
 - Comparison of health policies regarding Rx-to OTC switches in Europe
- **Pricing and reimbursement**
 - Analysis of decision-making processes and key decision criteria re. pricing and reimbursement
 - Study of the copayment policies of supplementary health insurance funds re. drugs according to the reimbursed level by the Social Insurance

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

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

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

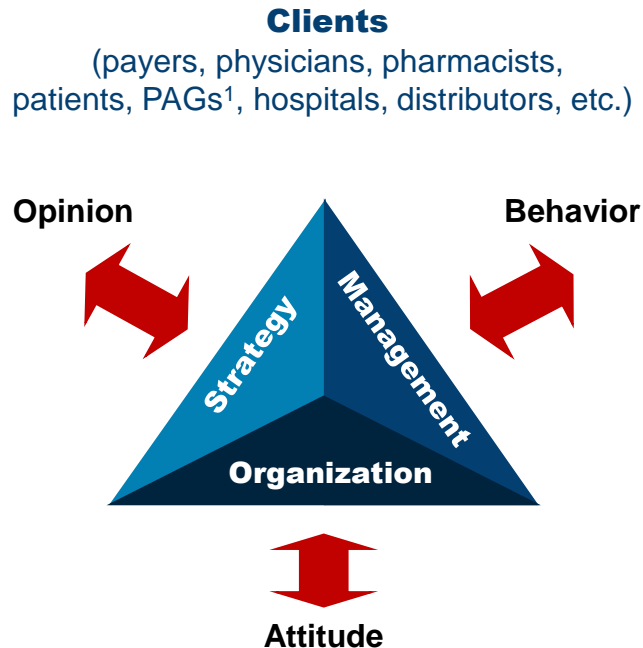


Smart Pharma Consulting is used to collecting and analyzing information about all pharma companies clients involved on the retail and the hospital markets

Clients

Market studies targeted at clients

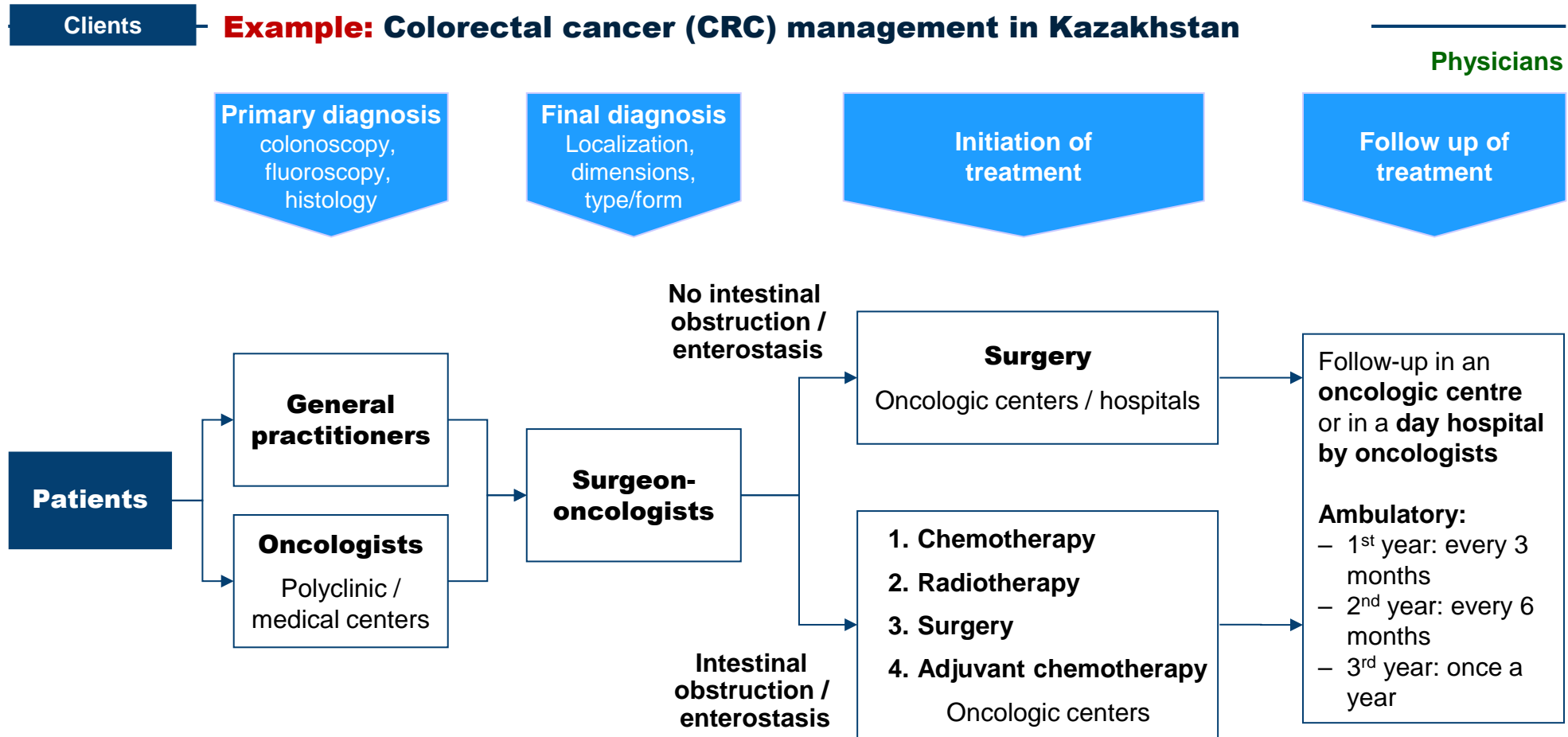
Illustration



Types of studies recently undertaken

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

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



Smart Pharma Consulting assesses regularly the degree of physicians preference for competing brands with the help of the “ Brand Preference Mix” concept¹

Clients

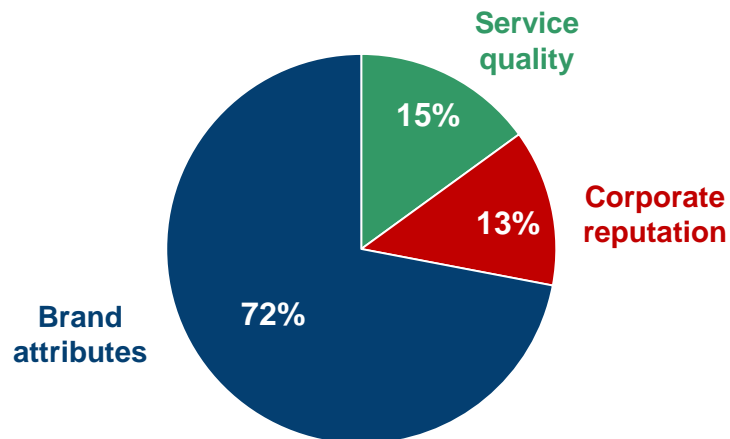
Example: Assessment of brand preference in the respiratory market

Physicians

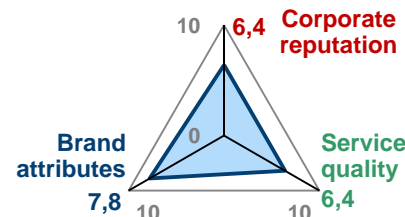
The Brand Preference Mix (BPM) helps determine the key prescribing drivers that can be activated to enhance prescribers preference for a brand, and thus increase its market share

General Practitioners

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



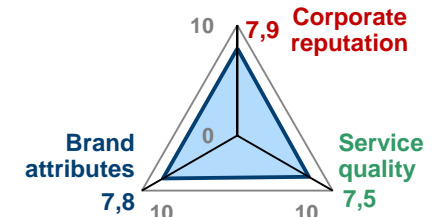
COMPANY A



BPM Index calculation:

$$(72\% \times 7.8) + (15\% \times 6.4) + (13\% \times 6.4) = 7.4$$

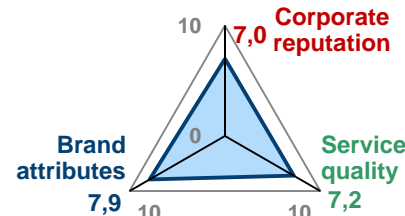
COMPANY B



BPM Index calculation:

$$(72\% \times 7.8) + (15\% \times 7.5) + (13\% \times 7.9) = 7.8$$

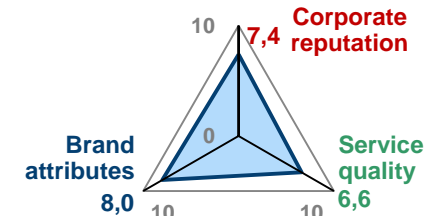
COMPANY C



BPM Index calculation:

$$(72\% \times 7.9) + (15\% \times 7.2) + (13\% \times 7.0) = 7.7$$

COMPANY D



BPM Index calculation:

$$(72\% \times 8.0) + (15\% \times 6.6) + (13\% \times 7.4) = 7.7$$

The in-depth knowledge and understanding of the market, through regular studies, enables Smart Pharma Consulting to produce complex and insightful analyses

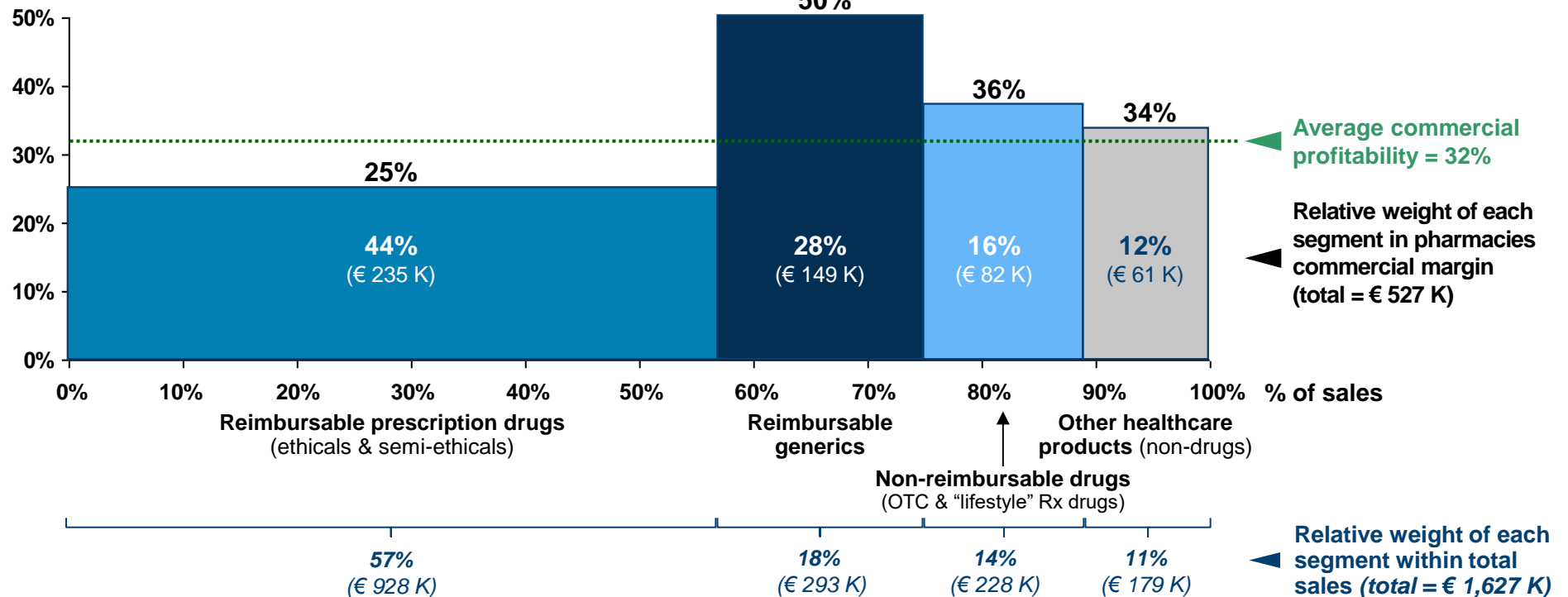
Clients

Example: Economic structure of retail pharmacies in France

Pharmacists

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

Average profitability by segment



Source: Smart Pharma Consulting

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

Clients

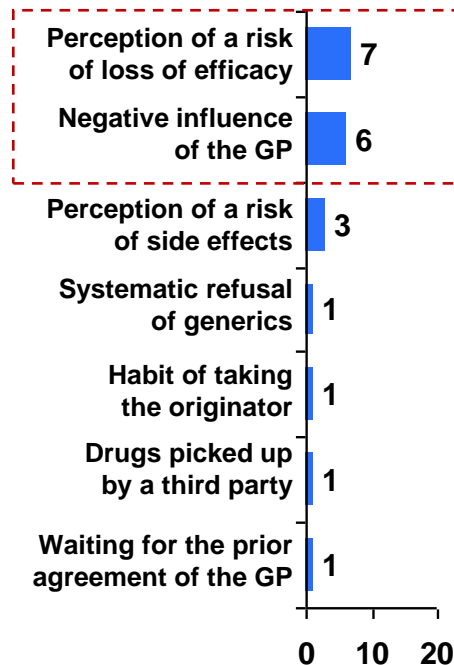
Example: Generics substitution refusal by patients

Patients

“Why do you refuse generics substitution?”

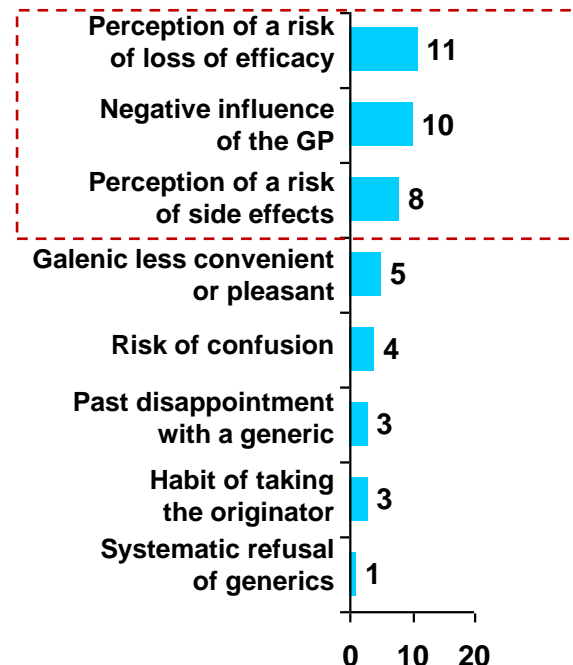
DUROGESIC

Number of quotes



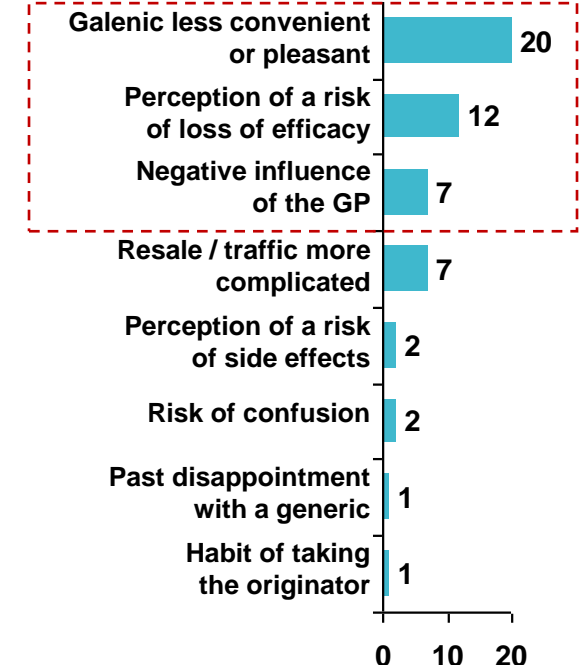
RISPERDAL

Number of quotes



SUBUTEX

Number of quotes

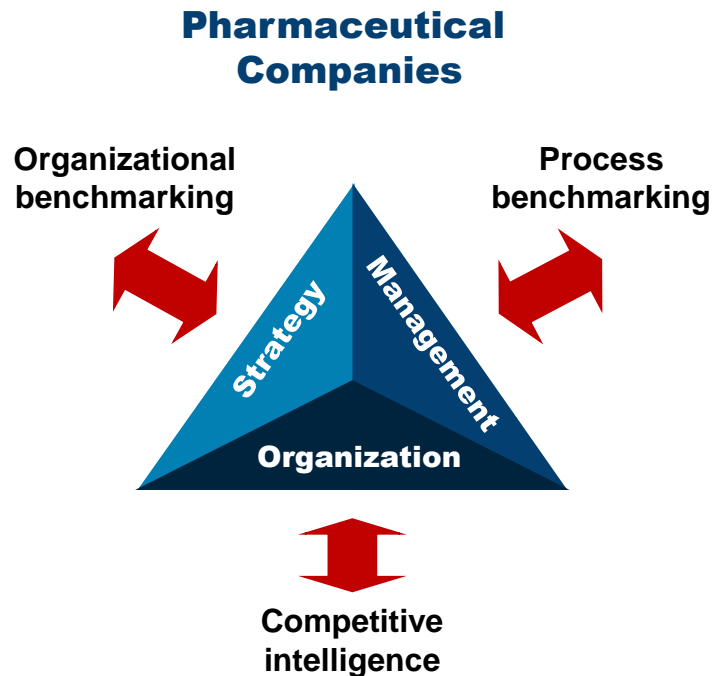


Smart Pharma Consulting carries out various types of benchmarking and competitive intelligence studies in the pharmaceutical sector, following a strict code of ethics

Competitors

Market studies on competitors

Illustration



Types of studies recently undertaken

- **Organizational benchmarking**
 - Surveys on organizational models
 - Surveys on different jobs in the pharmaceutical industry
 - Investigation of headcounts and the resources allocation
- **Process benchmarking**
 - Best practices identification
 - Surveys on adoption of new sales and marketing tools (CRM, trigger marketing, digital media, etc.)
- **Competitive intelligence**
 - Identification of future entrants and impact assessment
 - Investigation of product launches (dates and conditions)
 - Promotional investments assessment
 - Pricing policy at hospital

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

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

Organizational benchmarking

	Pharma company A	Pharma company B	Pharma company C	Pharma company D	Pharma company E	Pharma company F	Pharma company G	Mean
	50 to 79 €M	20 to 49 €M	20 to 49 €M	50 to 79 €M	50 to 79 €M	80 to 120 €M	20 to 49 €M	
Sales								
General management	2	2	1.5	1.5	1.5	2	2	2
Marketing	6	7	3	5	6	10	5	6
Sales management	5	1	4	3	2	7	9	4
Medical	3	0	2.5	2.5	3.5	8	5	4
Finance	8	5	3	3	2.5	13	4	6
Regulatory affairs	2	12	2	0.5	8	12	4	6
Legal	0	0	0	0	0	2	2	1
Human Resources	2.5	2	1	3	1	6	4.5	3
Public affairs / Communication	0	0	0	0	0	0	0	0
Commercial excellence	0	0	0	0	0	8	0	1
Training department	0	0	0	1	0	0.5	0	0
Business Development	0	1	0	0	0	1	0	0
Market access	0	0	0	1	0	2	0	0
General services	1	1	0	0	0	3	0.5	1
Logistic / IT	0	0	2	0	0	7	0	1
R&D / Clinical studies	0	0	0	0	4	12	0	2
Total headquarters	29.5	31.0	19.0	20.5	28.5	93.5	36.0	37
Sales Reps – GPs	66	8	48	160	20	111	33	64
First line managers – GPs	6	1	0	16	3	13	4	6
Second line managers	0	0	4	2	0	2	0	1
Sales Reps – Specialists & hospital	11	10	0	10	0	6	0	5
First line managers – Specialists & hospital	0	0	0	1	0	1	0	0
KAM & others	0	0.5	0	0	0	0	3	1
Total field forces	83.0	19.5	52.0	189.0	23.0	133.0	40.0	77
Grand total	112.5	50.5	71.0	209.5	51.5	226.5	76.0	114
Number of therapeutic areas	8	5	5	7	1	9	4	6
Number of products	18	7	16	17	1	32	16	15

Source: Smart Pharma Consulting

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

Competitors

Example: Benchmarking of remote e-detailing practices

Process benchmarking

Context

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

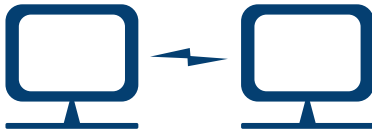
Objectives

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

Implementation

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

Results



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

Key learning

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

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

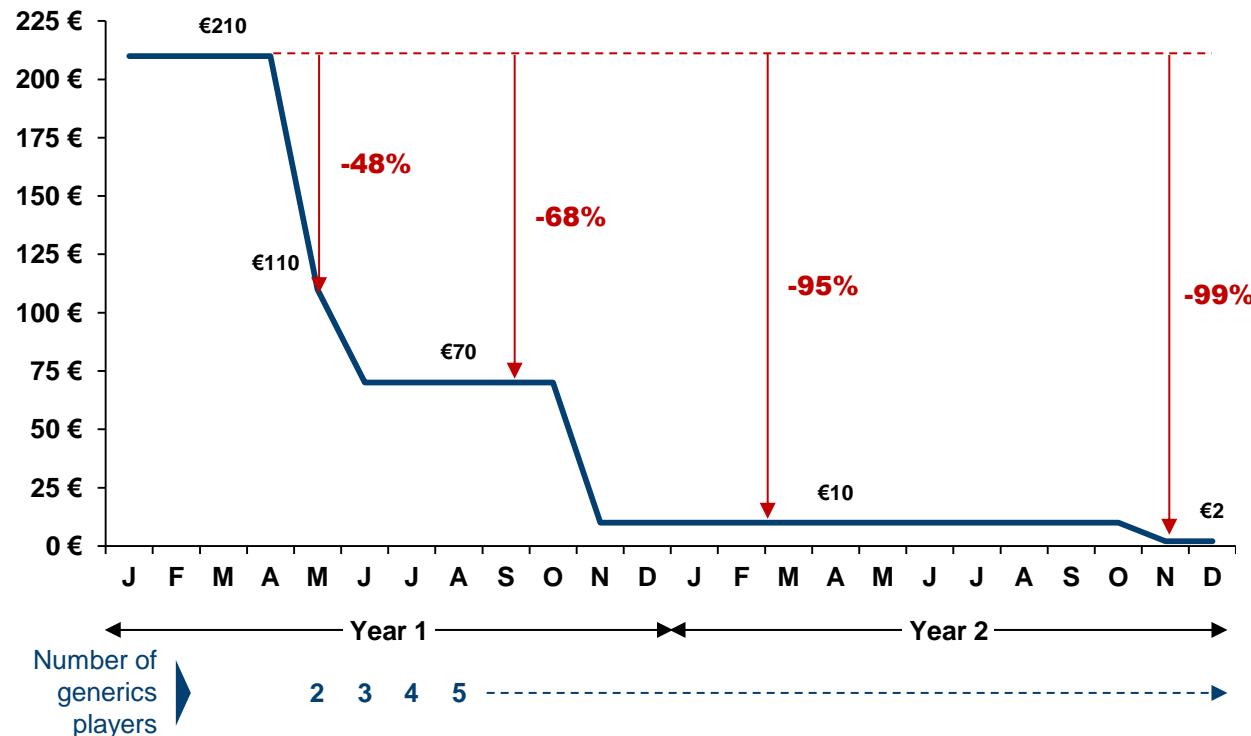
Competitors

Example: Hospital generics pricing

Competitive intelligence

Zometa case study in France

Estimated price on hospital market

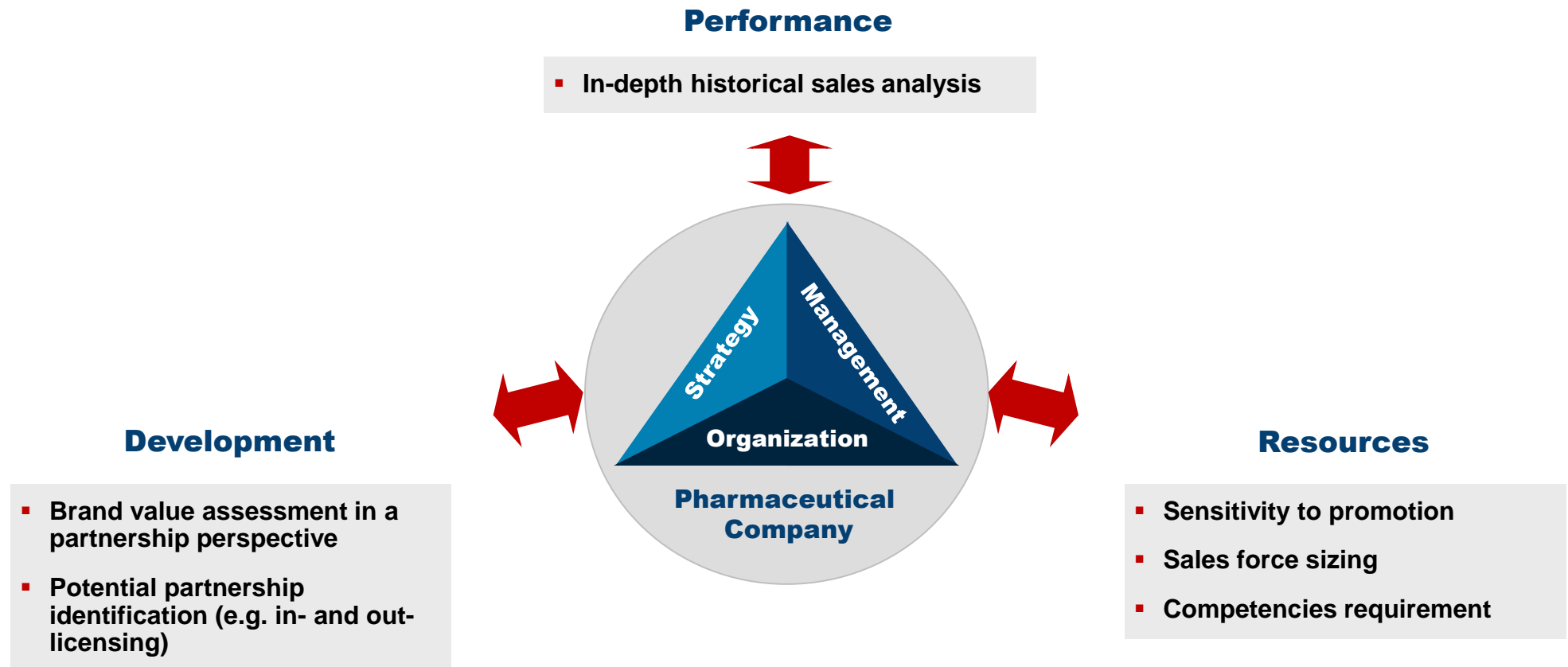


Comments

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

Smart Pharma Consulting rigorous and evidence-based analyses allow to transform information into actionable and added-value recommendations to pharma companies

Methodological approach

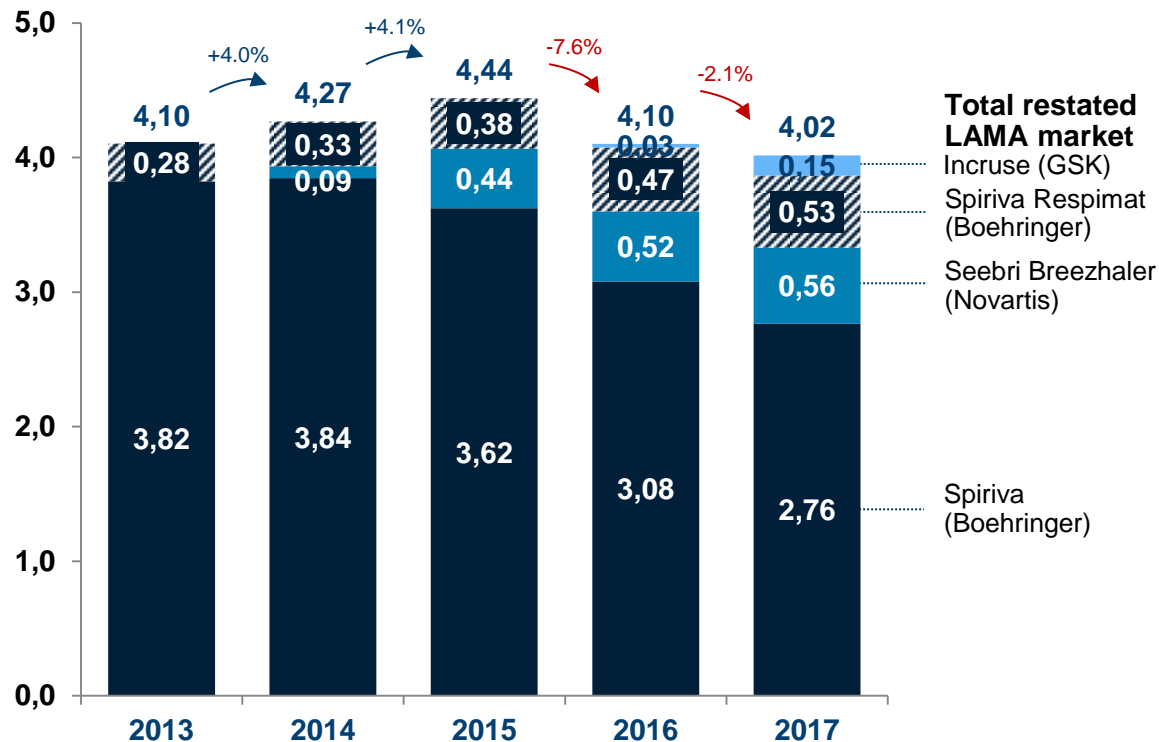


Smart Pharma Consulting regularly carries out in-depth brands analyses to get a comprehensive understanding of the dynamics of their performance

Performance

Example: Historical analysis of COPD products

Million packs (MAT¹ September)



CAGR ² 2013-2017	Evolution 2016-2017	Market share	
		2013	2017
-0.5%	-2.1%		
-	+69.6%	0%	3.8%
+17.6%	-	6.8%	13.3%
-	+8.2%	0%	14.1%
-7.8%	-10.2%	93.2%	68.9%

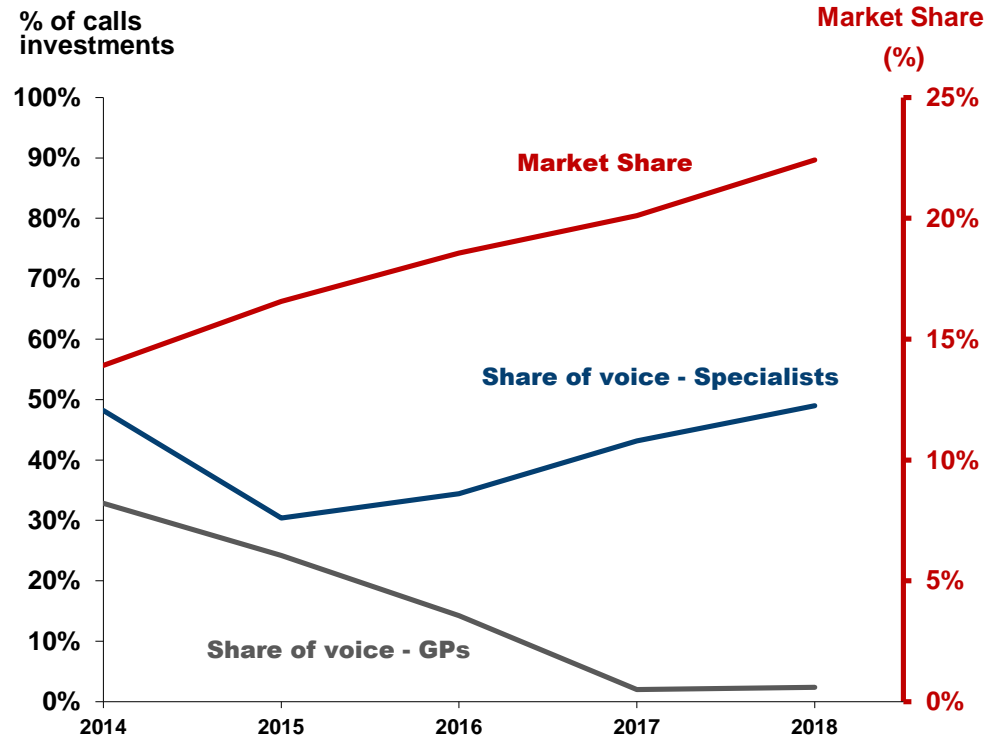
LAMA market defined here as the combination of all LAMA drugs specifically prescribed in COPD

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

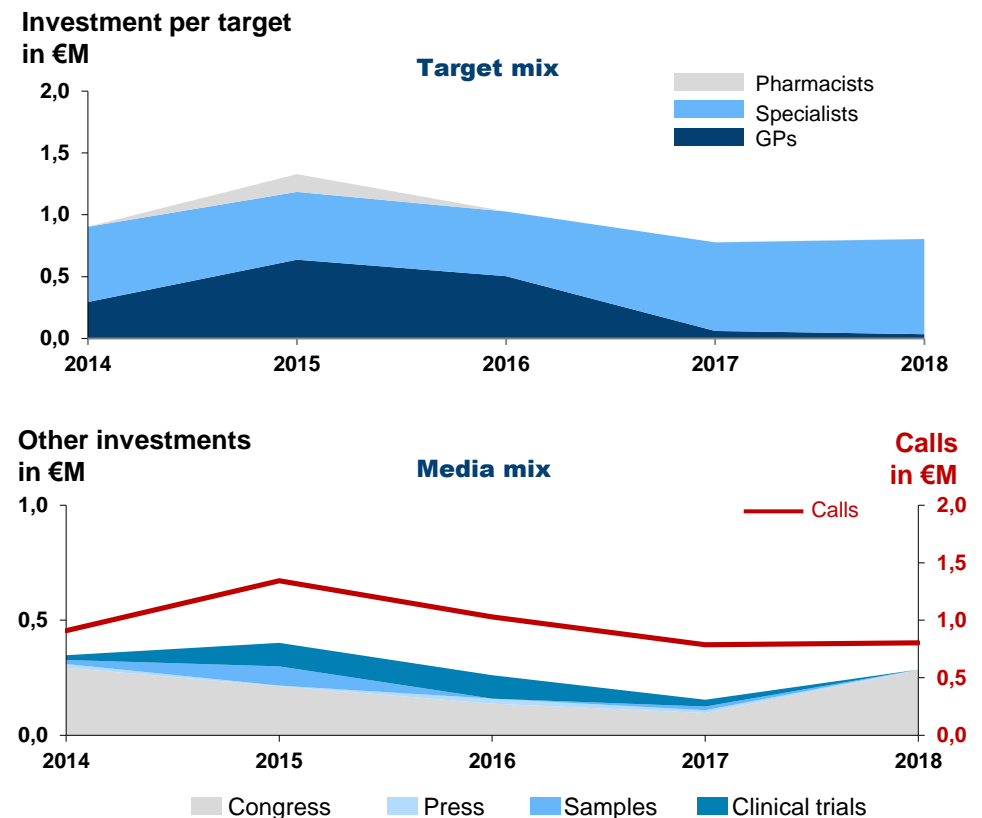
Resources

Example: Sensitivity to promotional investments

Performance & share of voice



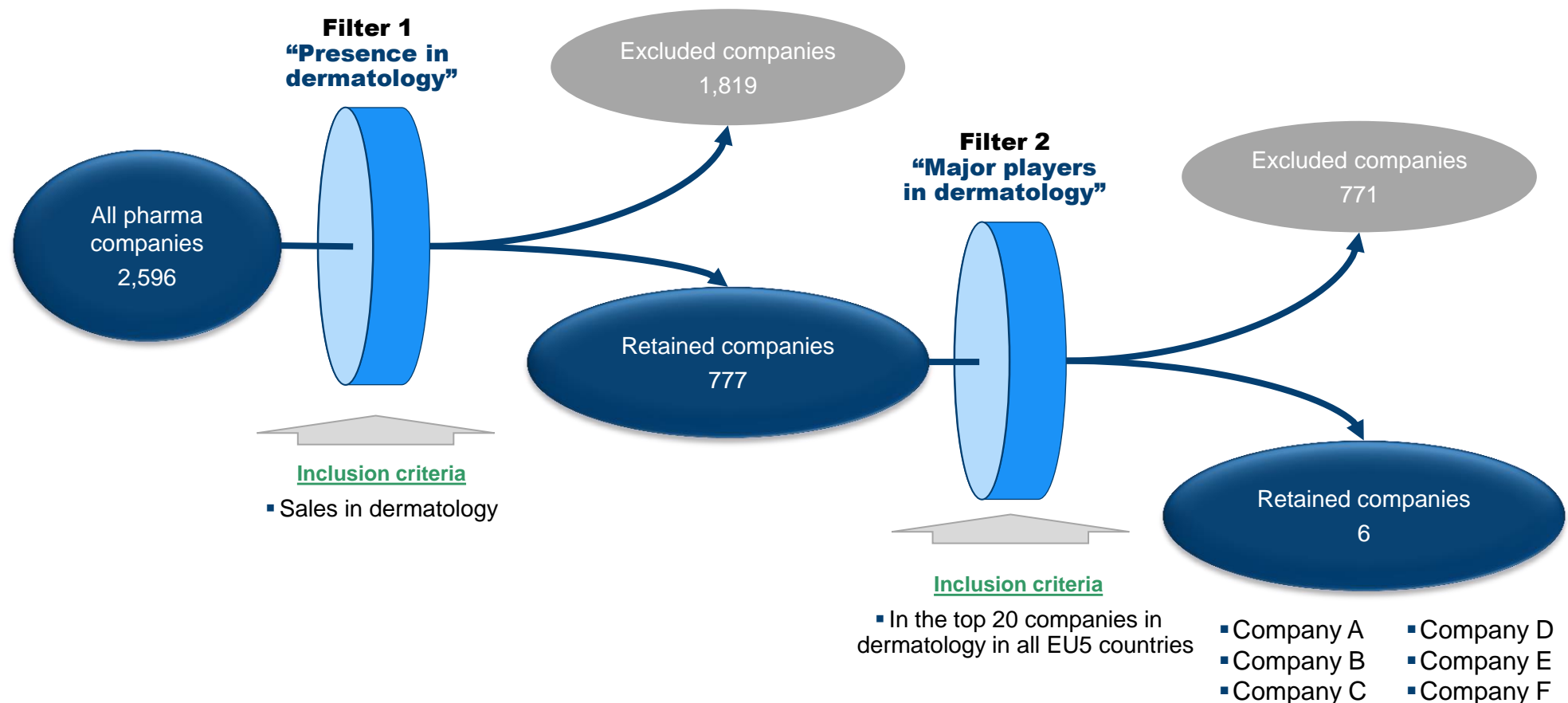
Promotional mix



Based on rigorous market analyses and an effective methodology¹, Smart Pharma Consulting can help identify potential partners for in- or out-licensing deals

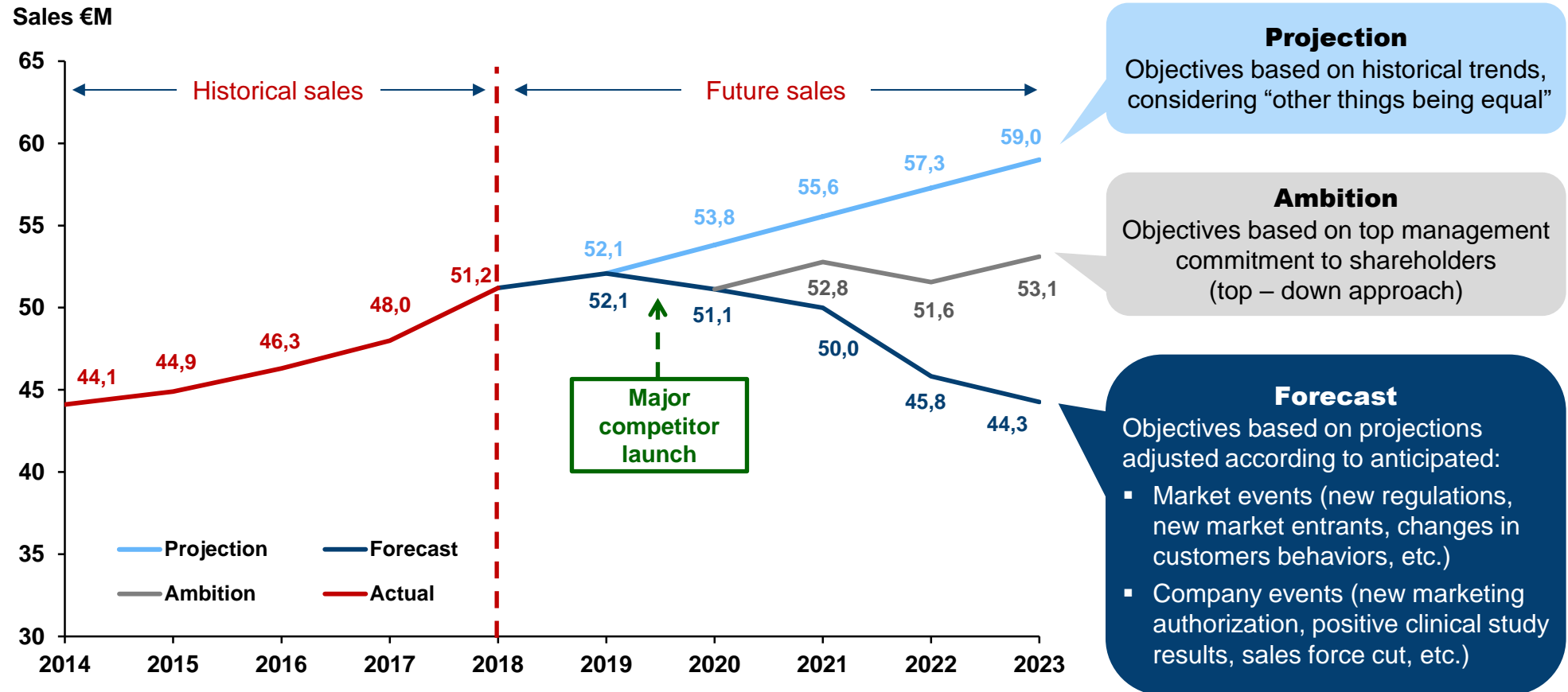
Development

Example: Identification of partners for an out-licensing deal



Smart Pharma Consulting is regularly asked by pharma companies to build scenarios to estimate sales and profits objectives according to the forecast method

Methodological approach



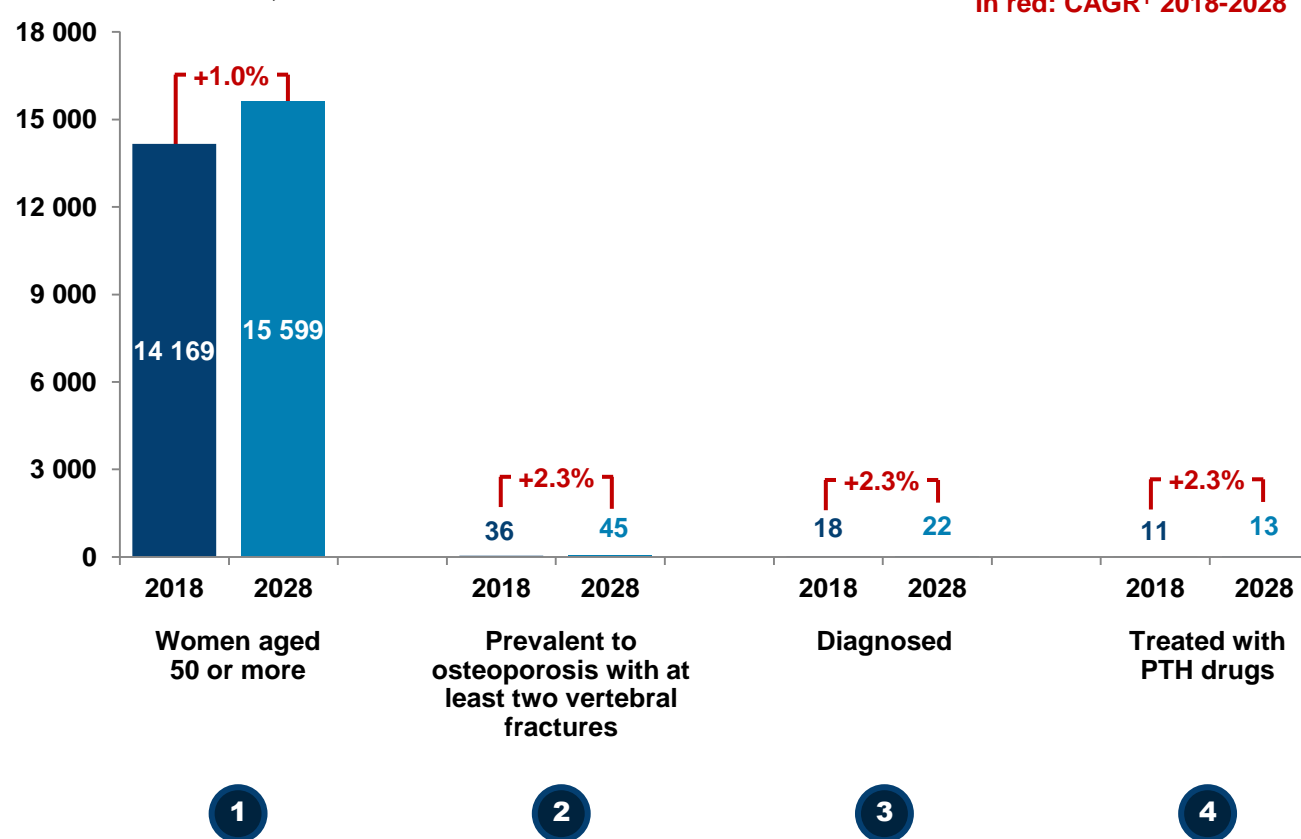
Source: Smart Pharma Consulting

A patient approach based on epidemiological data, diagnosis and treatment rates can be applied to estimate the evolution of a market size and of a brand market share

Example: Sales forecasting in the osteoporosis market

Patient approach

Number of women, in thousands



Comments

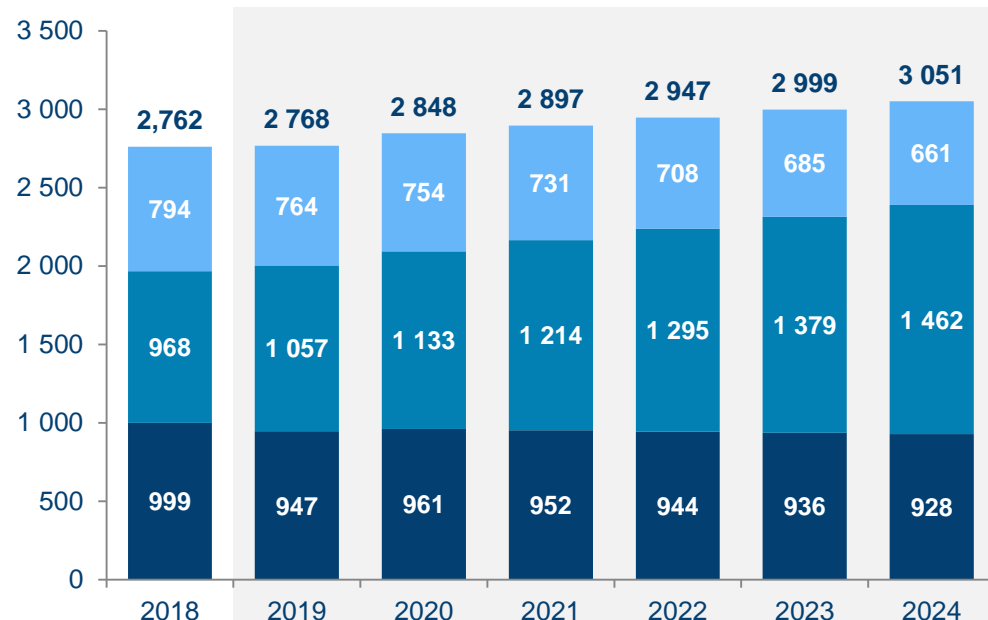
- **Prevalence** (+2.3% on average per year) **increases faster** than the total **population of women aged 50 or more** (+1.0% p.a.) because of a mixed effect :
 - **Ageing effect (baby boomers)**: women aged **75 and more** will represent **~31%** of the women aged 50 and more in **2028**, vs. **~27%** in **2018**
 - In addition, the **prevalence** rate within women aged **75 and more** (**~0.85%**) is much higher than the prevalence of women **aged between 50 and 74 years** (**~0.04%**)
- **Diagnosis** and **treatment rates** have been maintained at a **stable rate** over the period, in accordance with interviewed KOLs feedback:
 - **Diagnosis** rate: **50%** of prevalent women
 - **Treatment** rate: **60%** of diagnosed women

A market approach based on the adjustment of historical sales projections can also be applied to estimate the dynamics of a brand on its market

Example: Sales forecasting in the oncology market

Market approach

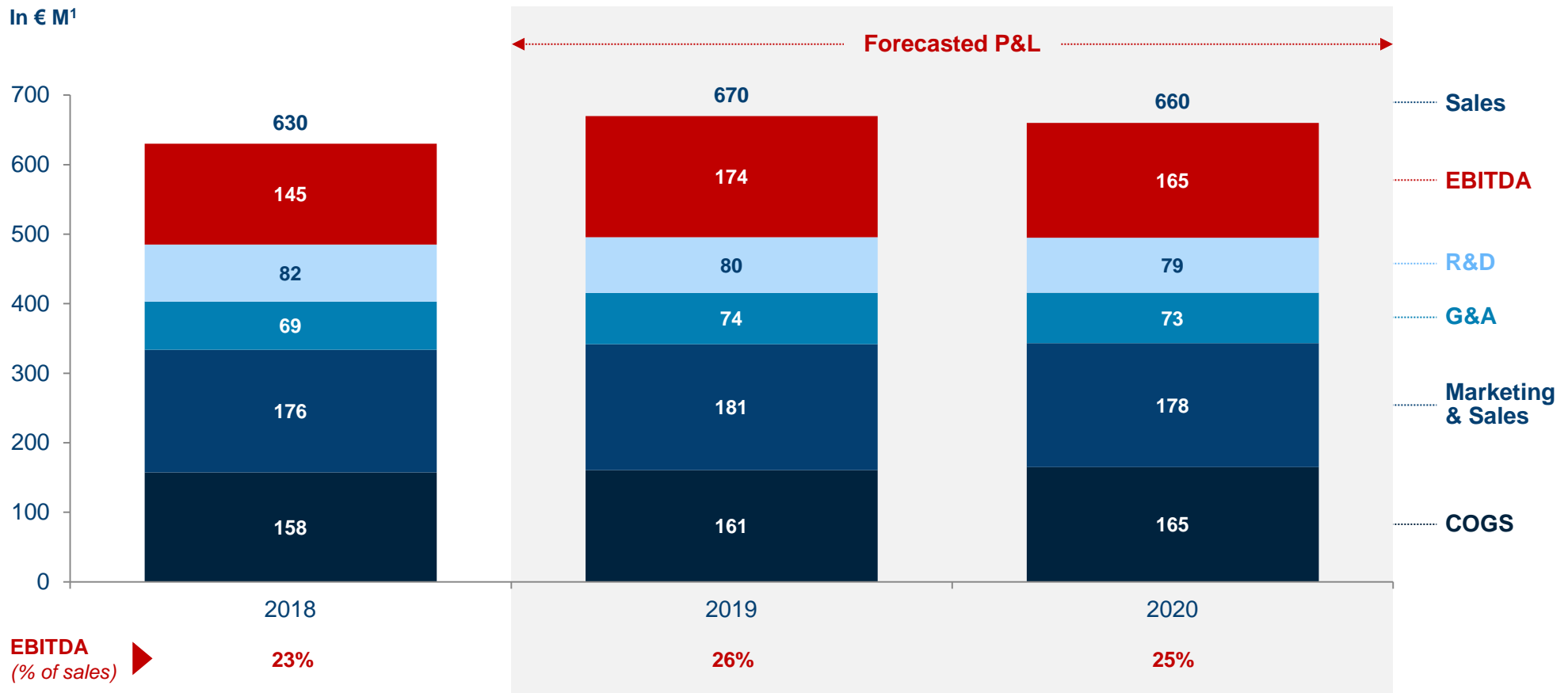
Sales in '000 units



	CAGR ¹ 2018-2024	Market share		
		2018	2021	2024
Total market	+1.7%			
Product A	-3.0%	28.8%	25.2%	21.7%
Product B	+7.1%	35.1%	41.9%	47.9%
Product C	-1.2%	36.2%	32.9%	30.4%

Smart Pharma Consulting can develop for pharma companies models to forecast the potential margin of selected products

Example: Profit forecasting for a CNS product

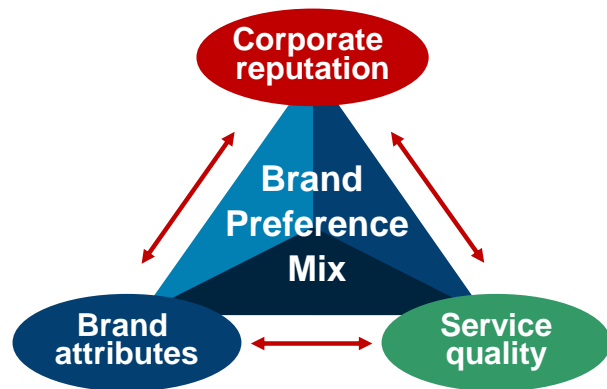


Smart Pharma Consulting proposes highly effective positioning and segmentation methods that are associated with specific data collection about customers

Positioning & Segmentation studies

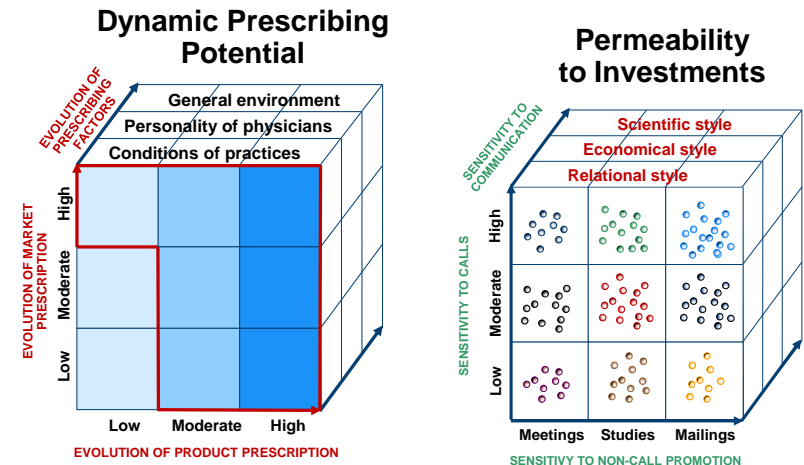
Examples of applications to Physicians

Brand Preference Mix (BPM)¹ – Positioning



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

Behavioral Prescriber Segmentation (BPS)¹



- The BPS optimizes investment efficiency by considering:
 1. Factors that drive the dynamics of prescriptions²
 2. Prescribers' personalities
 3. Prescribers' permeability to investments³

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

The ELITE Program¹ enables med reps to interact more efficiently with prescribers and to optimize the prescription share of the brands they promote

Sales force effectiveness studies

Example of applications to Sales force effectiveness

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



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

The “Market Analysis & Forecasting” masterclass has been designed for participants looking for robust and simple tools, and wishing to strengthen their analytical skills

Masterclass¹: Market Analysis & Forecasting Excellence

Day 1: Market Analysis

- 9:00 Introduction to the masterclass
- 9:10 Review and discussion of analytical concepts, methods and tools sent to participants as a pre-read
- 10:30 Lecture by and discussion with an expert:
“Review of the most advanced market analyses – Lessons from non pharma markets”
- 11:45 *Break*
- 12:00 Case study #1: **Market & brand dynamics evaluation:**
 - Stakeholders behaviors analysis²
 - Key market drivers & barriers analysis
 - Sensitivity of brands to operational³ investments
 - From data analysis to decision making
- 13:00 *Lunch*
- 14:00 Case study #1: cont.
- 16:00 *Break*
- 16:15 Presentation of the case study outputs, discussion and agreement on key learnings
- 17:45 End of the 1st day

Day 2: Forecasting

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

The French Pharma Market 2018 – 2023 Prospects

Excerpts



**Strategic Implications
for Pharma Companies**

Business Report

March 2019

1, rue Houdart de Lamotte – 75015 Paris – France
Tel.: +33 6 11 96 33 78 – Fax: +33 1 45 57 46 59
E-mail: jmpeny@smart-pharma.com – Website: www.smart-pharma.com

**Report for sale: Please contact:
Jean-Michel Peny – Phone: +33611963378 – E-mail: jmpeny@smart-pharma.com**

Introduction

- Foreword
- International healthcare expenditure

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Section 1. The French healthcare system

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- LFSS 2017 key articles regarding drugs and pharma companies
- LFSS 2018 key articles regarding drugs and pharma companies
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This report analyzes the current situation and the key trends on the French Pharma market by the end of 2023 to provide pharma companies with key strategic insights

2019 – 2023 French pharma market prospects & strategic implications

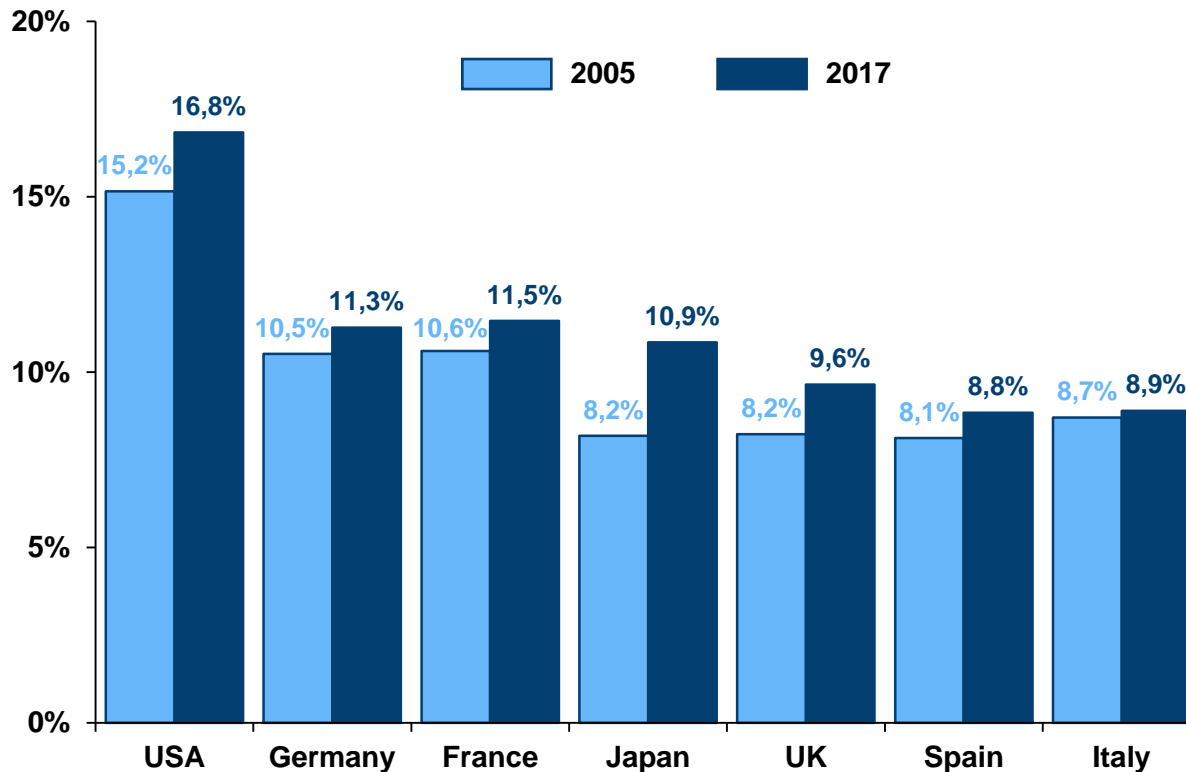
- Despite an ever-tougher environment, the French pharma market should remain a key priority for pharma groups
- Smart Pharma Consulting proposes to address the following key issues related to the French healthcare system and pharma market evolution by the end of 2023, to better grasp its strategic impacts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



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

Healthcare expenditure as a percentage of GDP (2017*)

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



* Note: Data 2015 (USA and Japan)

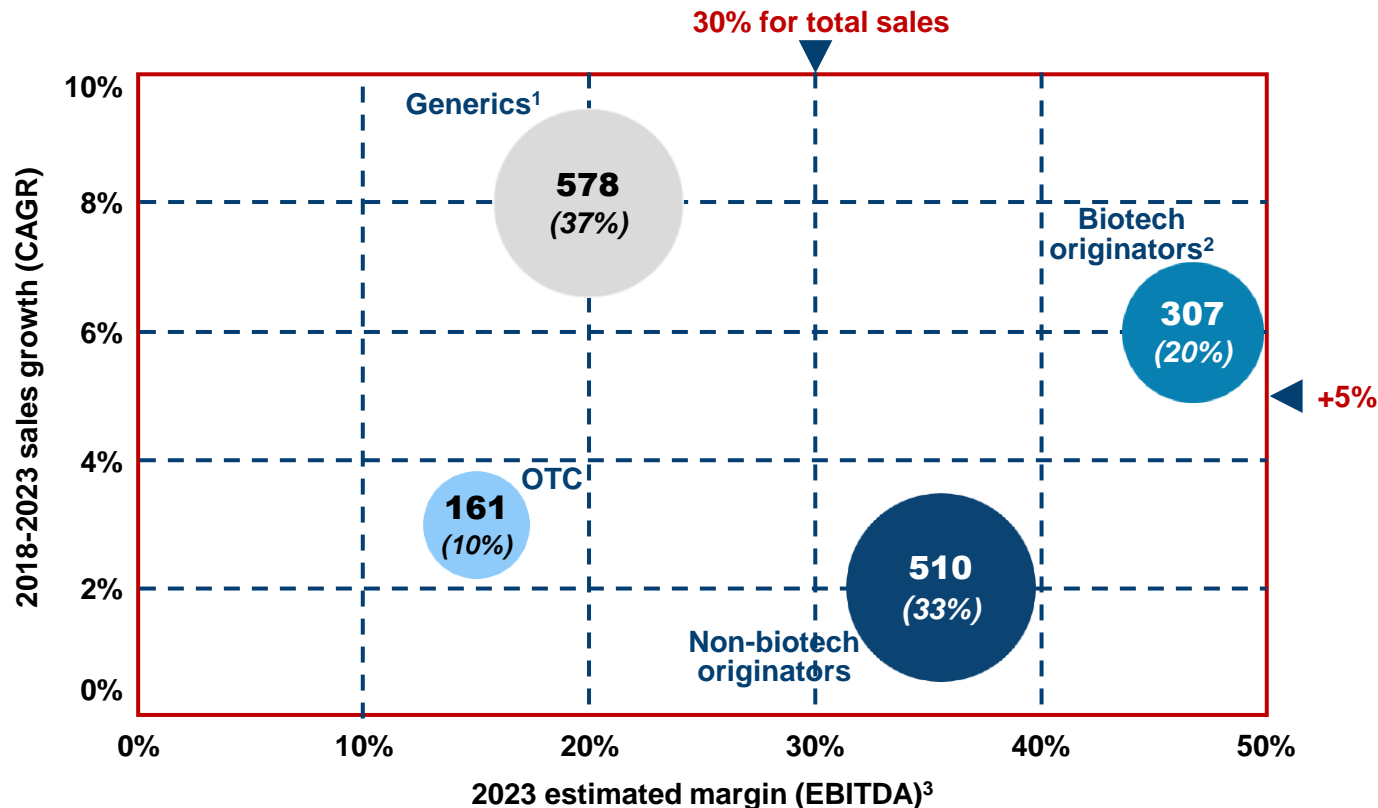
Sources: Health at a Glance, OECD (2018) – Government at a Glance (2017) – Smart Pharma Consulting analyses

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

¹ After social protection – ² After social protection and general public services

By 2023, the sales growth of the pharma market should be mainly driven by generics and biotech originators, but pharma companies should lose two points of profitability

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

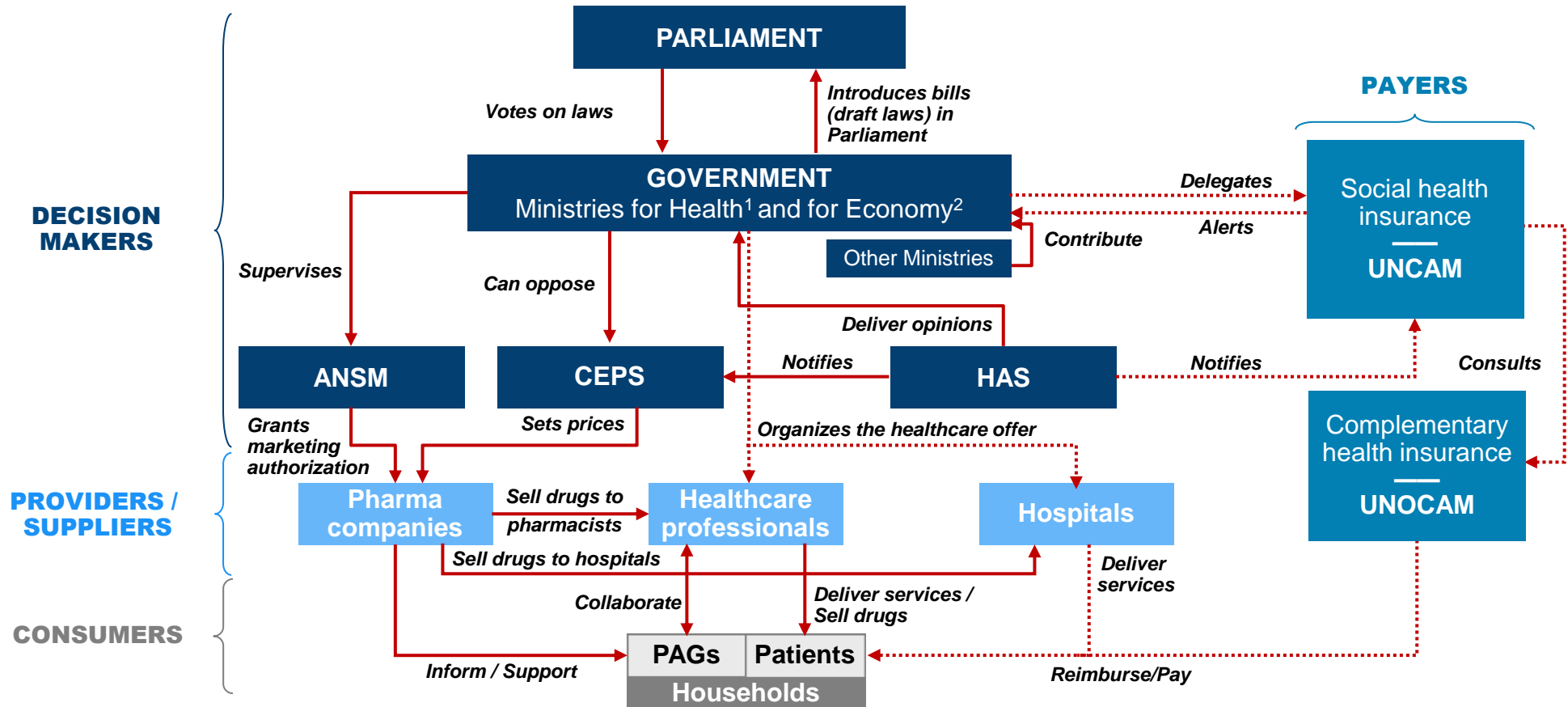


○ 2023 sales in USD B
(the total accounting for USD 1,556 B)

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

Stakeholders in the French healthcare system can be divided according to their role as decision makers, payers, providers / suppliers or consumers

Mapping of key stakeholders

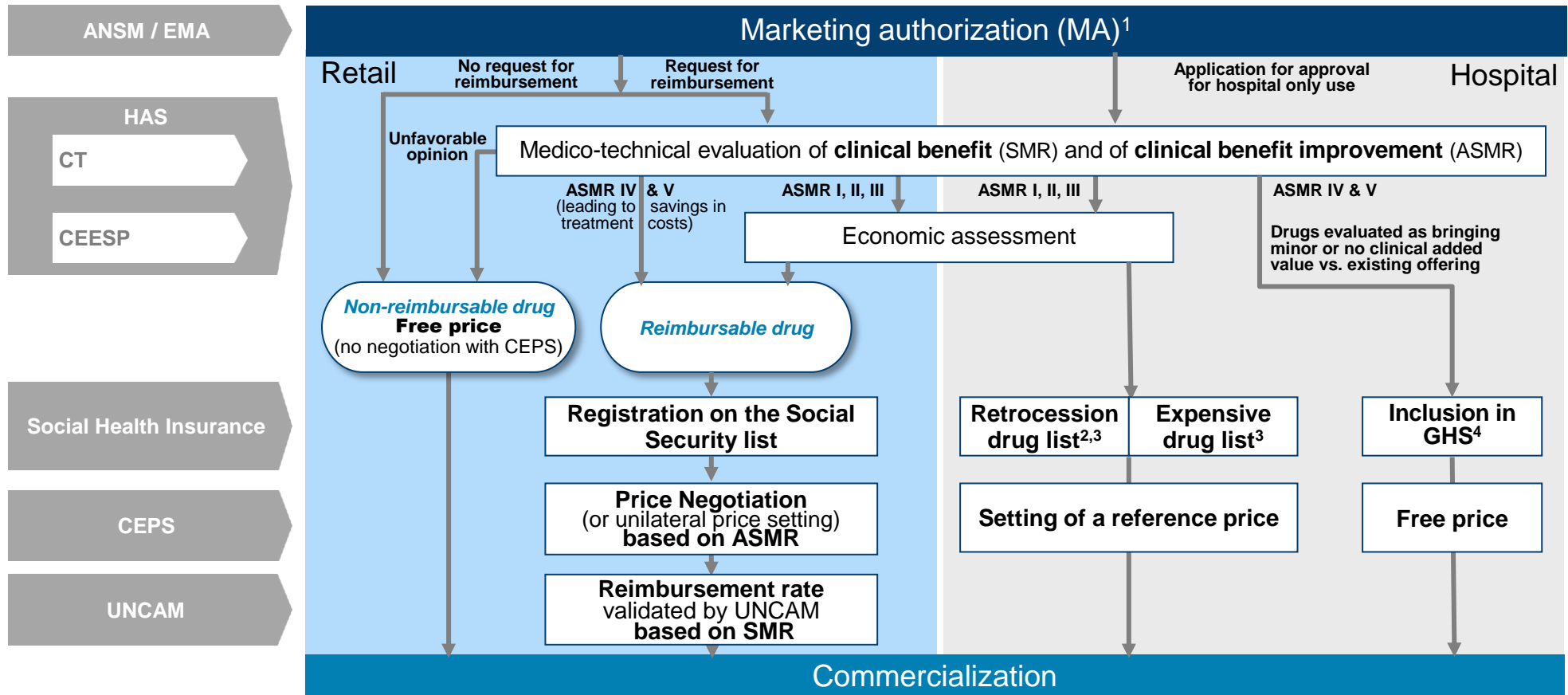


Sources: Smart Pharma Consulting analyses

¹ The exact name of this ministry is: Ministry of Solidarity and Health – ² The exact name of this ministry is the Ministry for the Economy and Finance which includes the budget and the industry

In France, various healthcare institutions are involved in the setting of the price and reimbursement rate after a drug has received its marketing authorization

Overall reimbursement and pricing processes

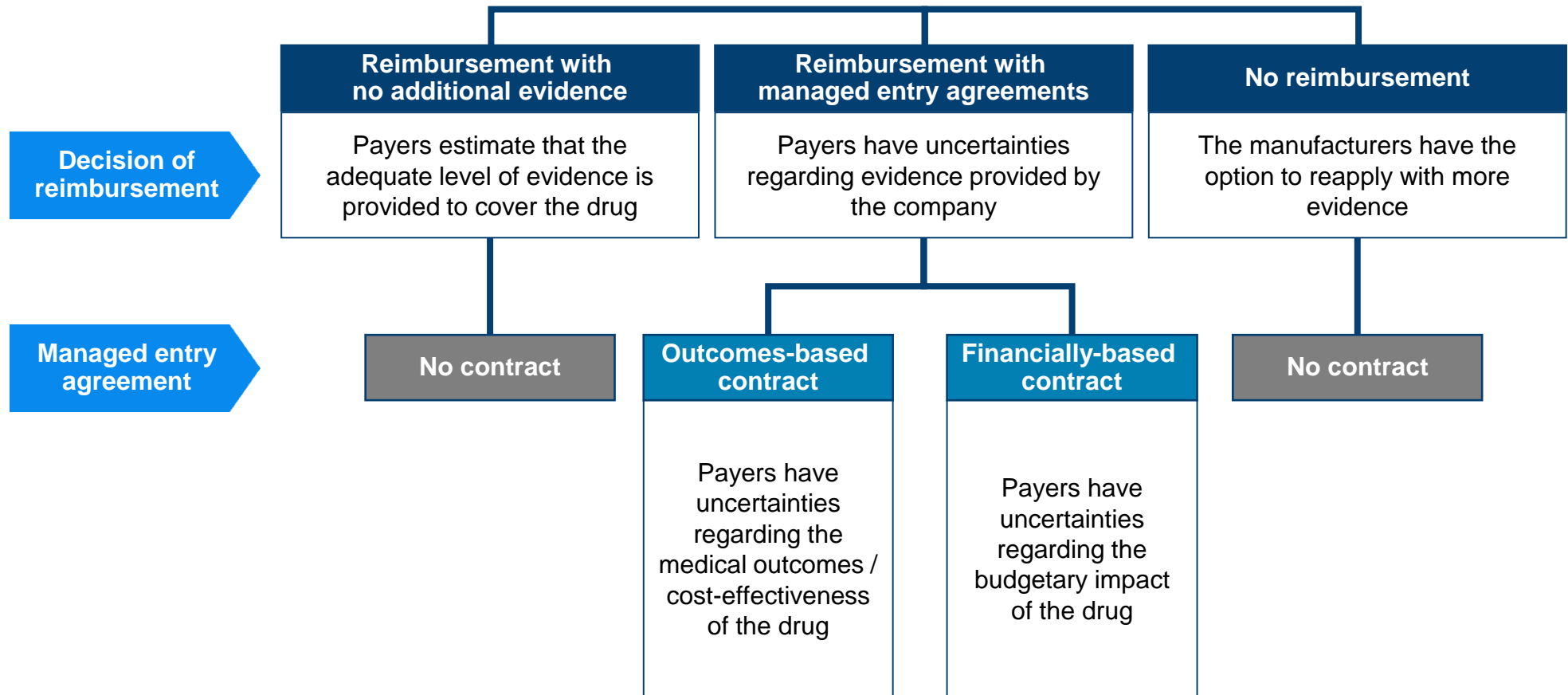


Sources: Directive "Transparence" 89/105/CEE and updates – www.ansm.sante.fr – www.leem.org – Smart Pharma Consulting analyses

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

Managed entry agreements may be considered by the CEPS when the level of medical evidence is too low and/or the financial impact is too high

CEPS – Options for a newly approved product



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

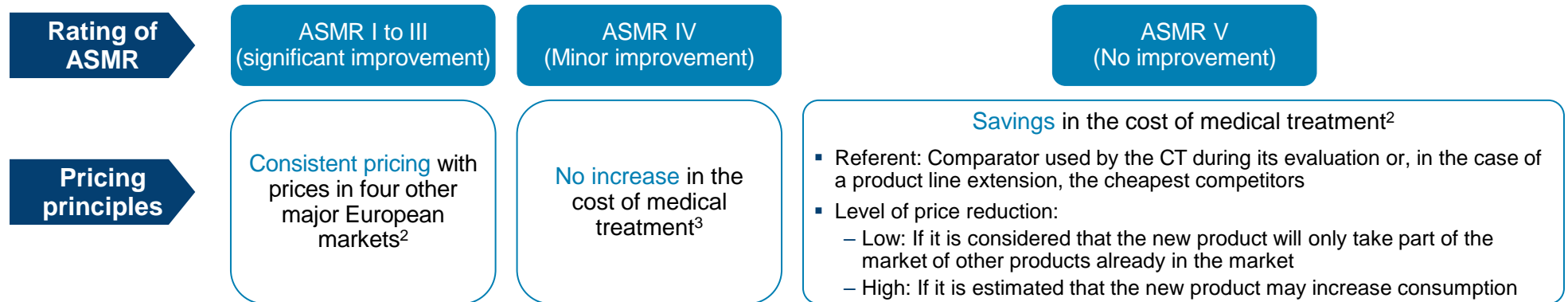
CEPS – Pros & Cons of managed entry agreements

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

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

The price level accepted by the CEPS (Economic Committee on Healthcare Products) depends on the level of ASMR granted by the Transparency Committee

CEPS – Price setting for reimbursable ambulatory drugs¹

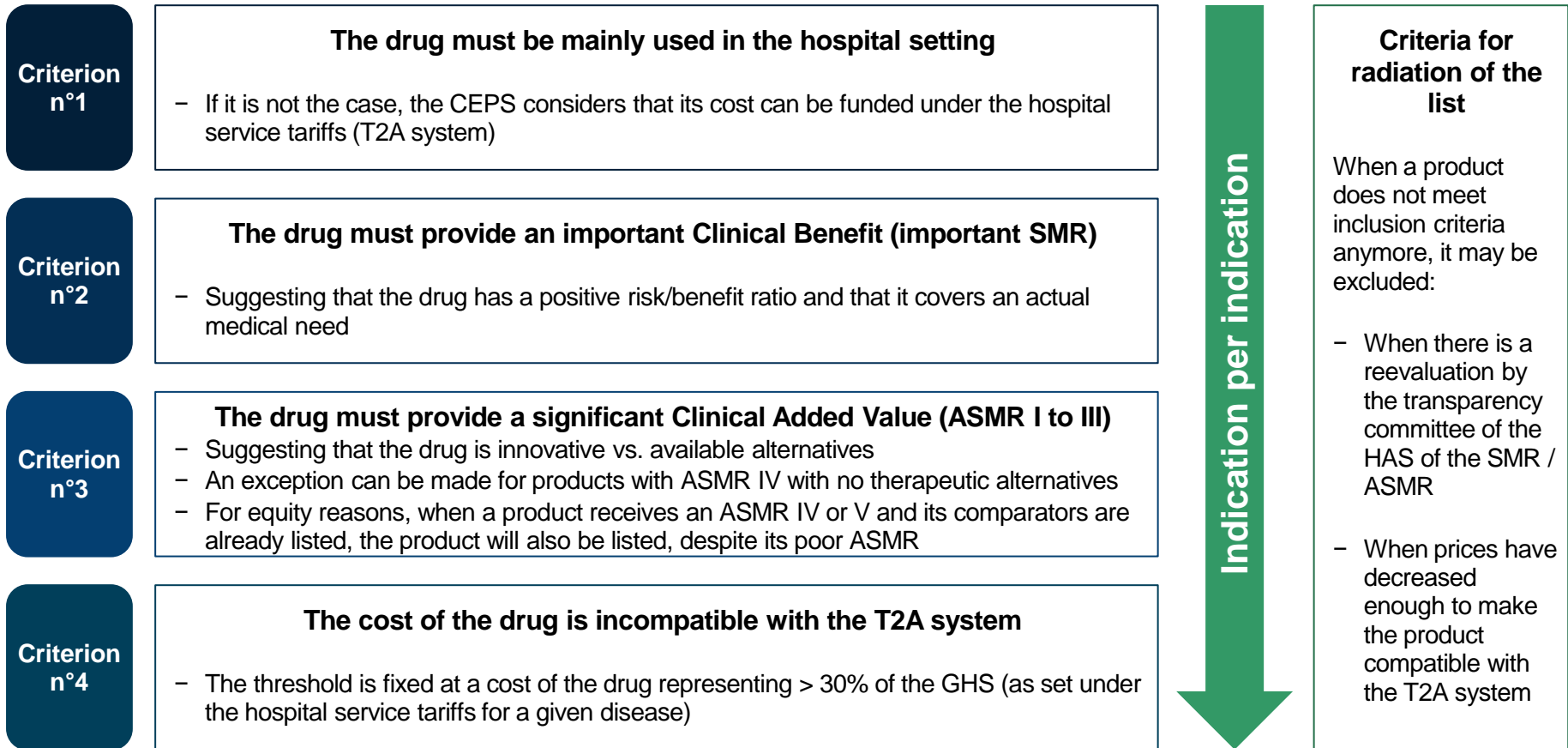


Specific clauses may be added to the price agreement between the CEPS and the pharma companies:

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

The criteria for the inclusion of a hospital drug on the list for invoicing on top of “T2A¹” are well defined since March 2016

Criteria for inscription on/radiation from the list on top of T2A¹ expensive hospital drugs

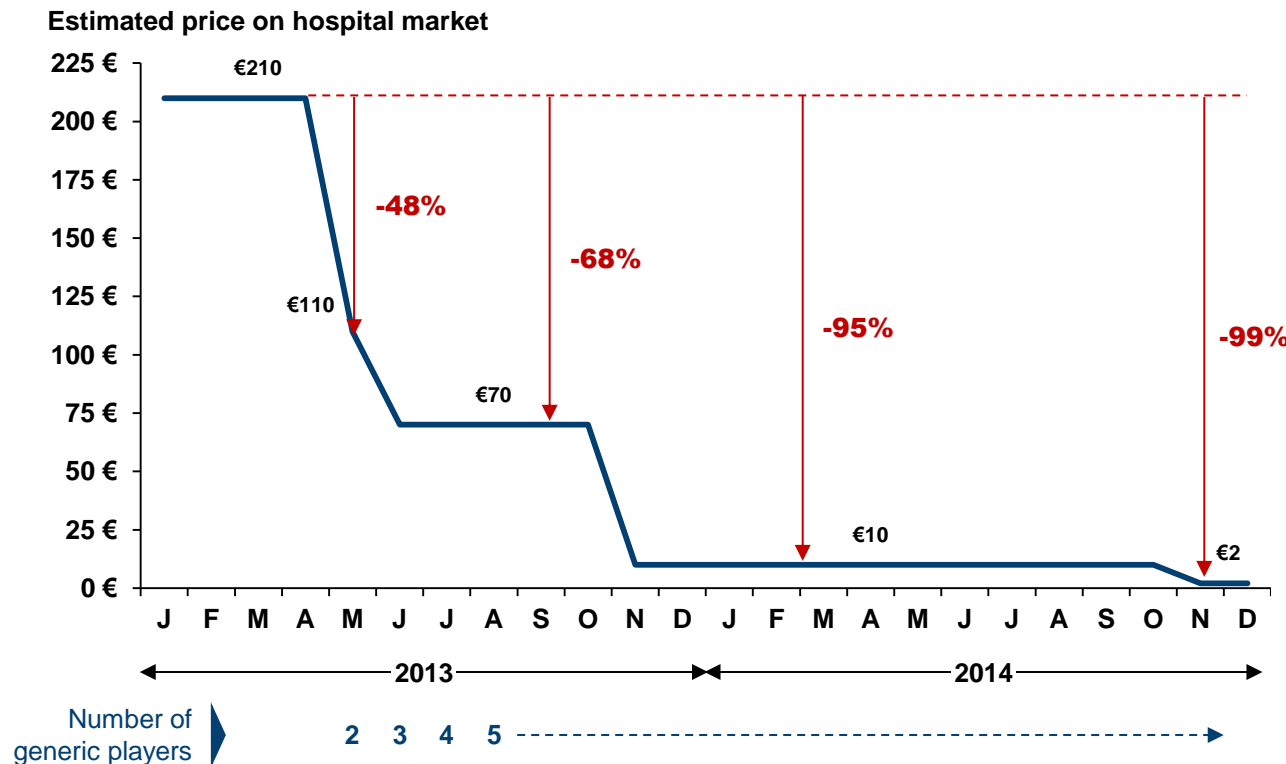


Sources: Decree of March 25th, 2016 regarding modalities of inscription to the “liste en sus” – Smart Pharma Consulting analyses

¹ Activity-based costing system similar to a Diagnosis related group-based funding

When the second generics company enters the market, the pricing strategy becomes even more aggressive

CEPS – Hospital generics pricing: Zolendronic acid (Zometa)

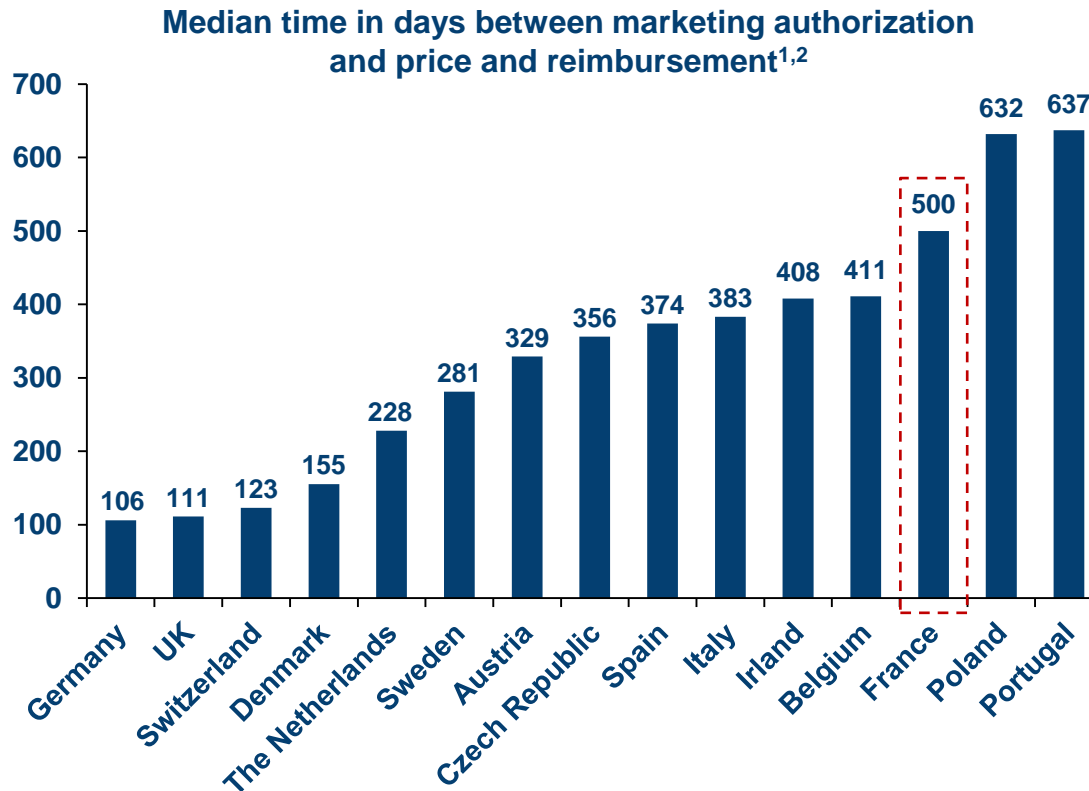


Comments

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

In France, pharma companies and patients must wait almost 17 months after marketing authorization to get a new drug reimbursed and launched¹

Average time to market – European comparisons



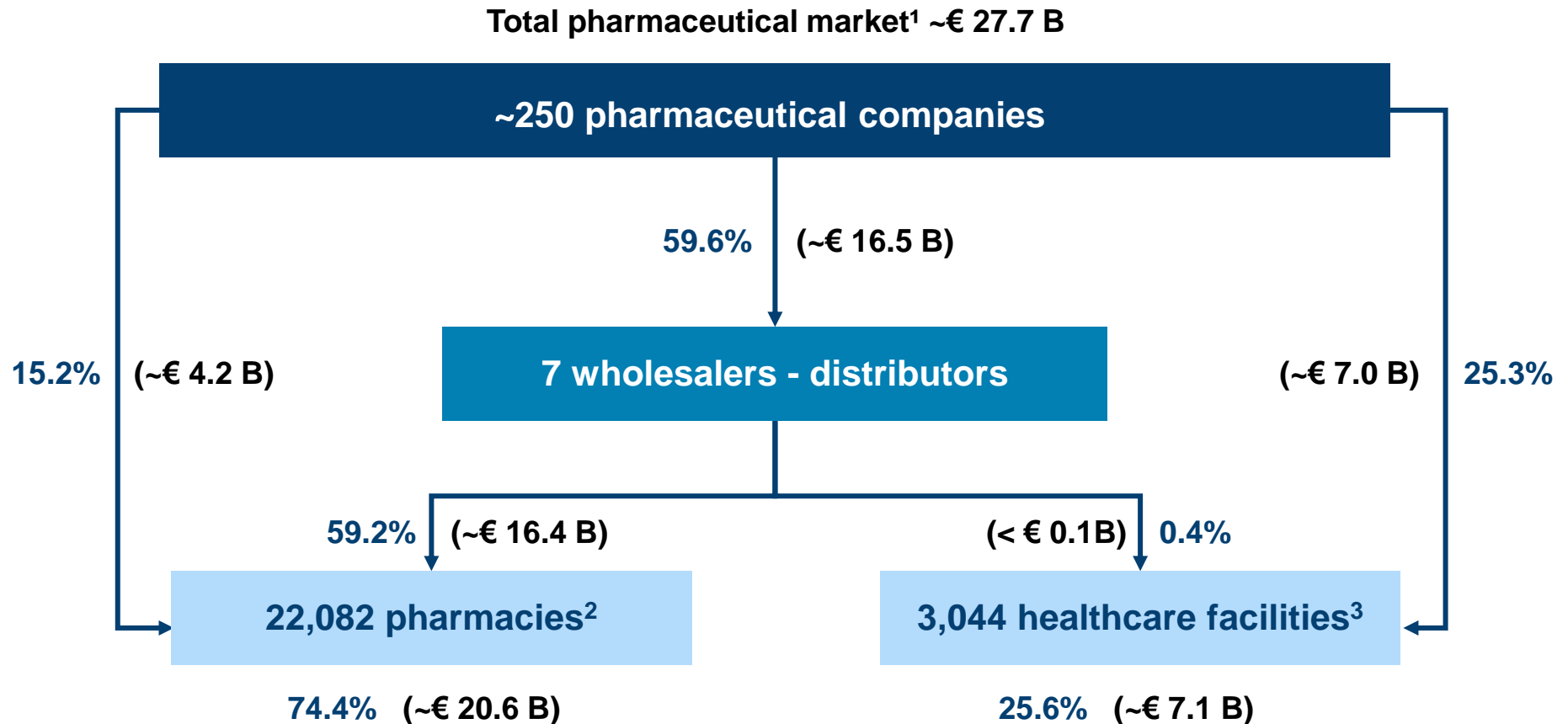
2017 analysis based on a sample of 146 products approved by EMA (European Medicines Agency) between January 2014 and December 2016

- 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 revenues¹
- The UK and Germany have no delay since the price and reimbursement negotiations occur once the product has reached the market

- In 2018, the LEEM (French association of pharmaceutical companies) has carried out a study on 67 new products, showing an average time between marketing authorization and price & reimbursement of 563 days

Drugs sold in retail pharmacies are mainly sourced from wholesalers / distributors, while hospital drugs are usually directly sourced from pharmaceutical companies

Drug supply chain (2018)



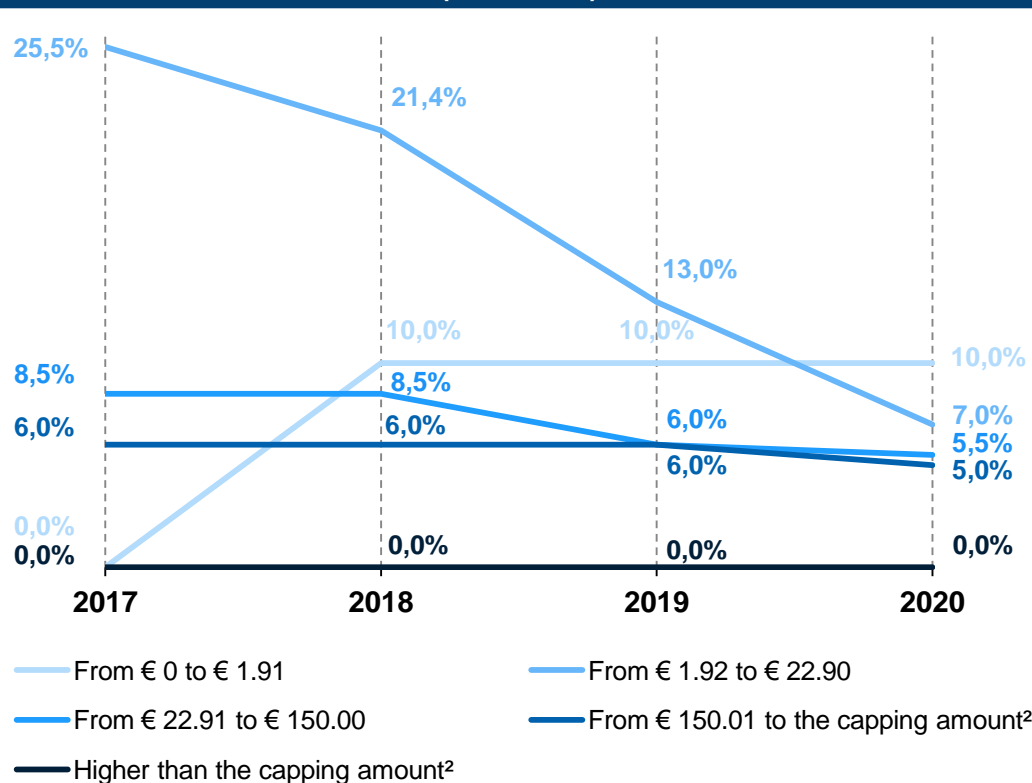
Sources: GERS dashboard (December 2018) – Leem (“Bilan Economique 2018”) – Ordre National des Pharmaciens (as of February 2019) – DRESS (2018) – Smart Pharma Consulting estimates

¹ Ex factory-price, including hospital rebates – ² ~70% belonging to Voluntary Trade Organizations – ³ Public and private

The revision of the smoothed digressive margin is part of a decorrelation process between the economy of retail pharmacies and the price of reimbursed drugs

11th amendment to the National Pharmaceutical Agreement

Evolution of the smoothed digressive margin on ex-factory price¹ (2017-2020)



- The main priority of the 11th amendment³ to the National Pharmaceutical Agreement is to change the remuneration of retail pharmacies and make them **less dependent on the price and volume of reimbursable drugs**
- Thus, it proposes **progressive transfer to new forms of remuneration** related to dispensing and to the improvement of patients management

New dispensing fees	2019 ¹	2020 ¹
Fees for the delivery of a prescription	€ 0.50	€ 0.50
Fees related to the age of the patient (youth children and elderly people)	€ 0.50	€ 1.55
Fees for the delivery of specific drugs (e.g. immunosuppressive drugs)	€ 2.00	€ 3.50

New missions	Remuneration (2019)
Medication reports for elderly people taking more than 5 drugs	€ 60 for the initial interview and then € 30 ⁴ or € 20 ⁴
Belonging to a primary care team	€ 420 per year
Share medical file	€ 1 per medical file opened

Sources: 11th amendment to the National Pharmaceutical Agreement (July 2017) – Official Gazette (September 2015, December 2017 and November 2018) – Le Quotidien du Pharmacien (January 2019) – 11th Meeting of the USPO (January 2019)

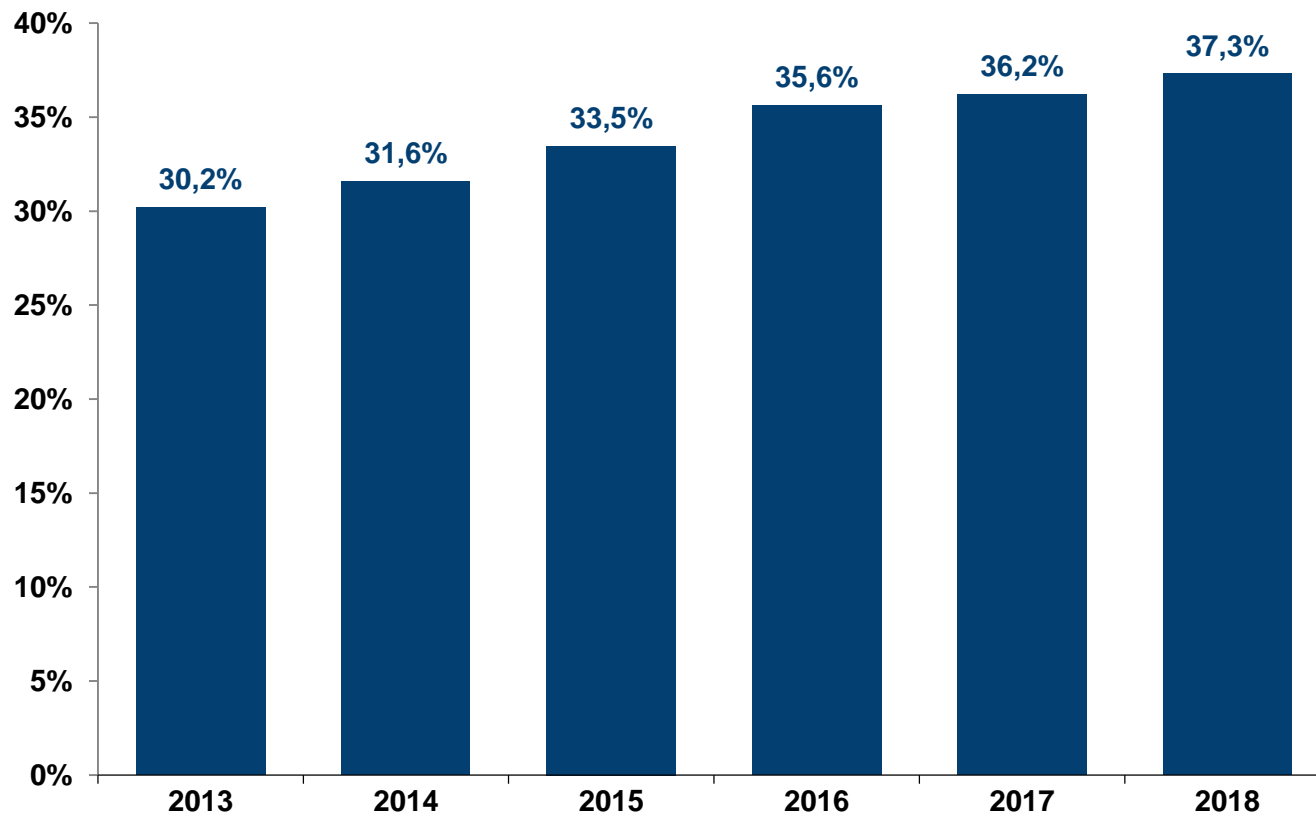
¹ VAT excluded – ² Amount from which the margin is capped: €1,500 in 2017, € 1,515 in 2018, € 1,600 in 2019 and €1,930 in 2020 – ³ The amendment was signed by only one of the three French pharmaceutical unions –

⁴ Whether new treatments are initiated in subsequent years or not

The LFSS 2019 introduced new measures at physician and patient level to increase the substitution rate and thus the level of generics penetration

LFSS 2019: New measures to boost generics penetration

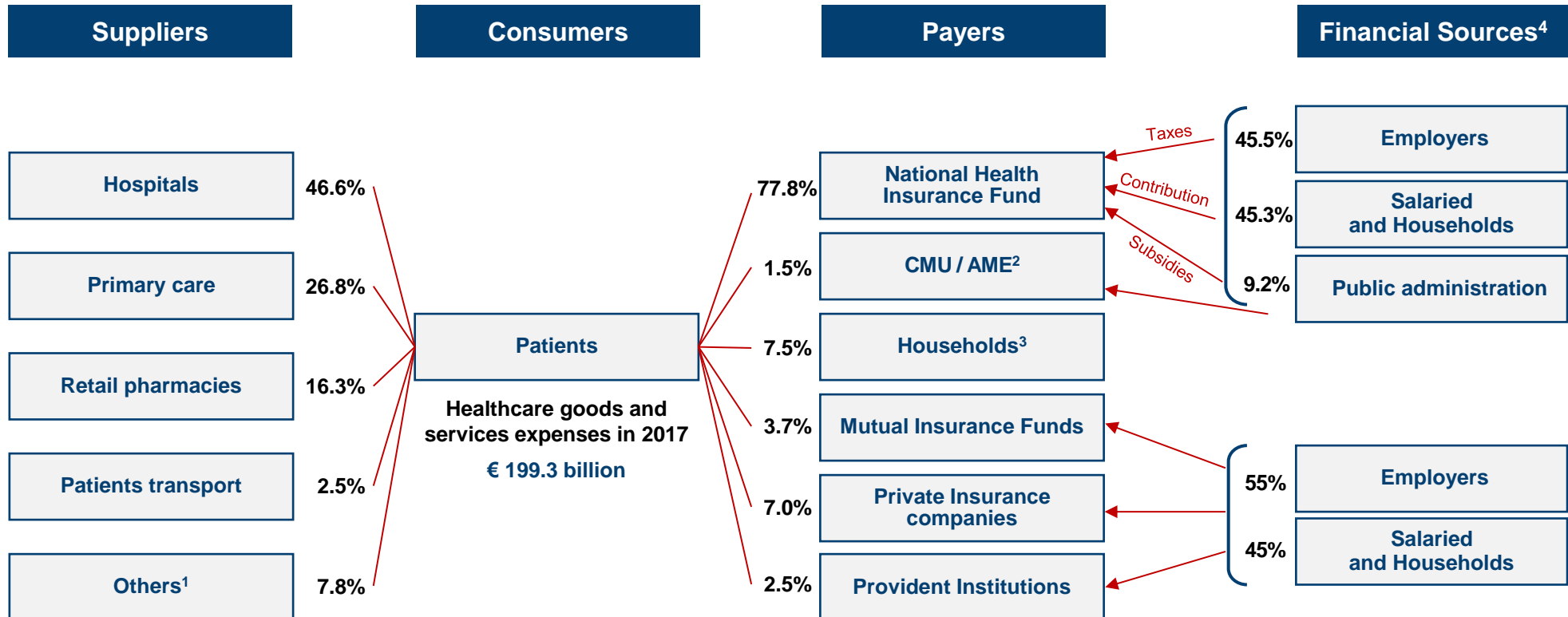
Generics penetration rate in volume in the retail reimbursable market



- In **2018**, generics accounted for **37.3%** of the total reimbursable retail market in volume (and **18.9%** in value)
- To **foster** the generics penetration rate, the **LFSS 2019** introduced:
 - The obligation for physicians to indicate on their prescription the **medical reason** why they refuse substitution, if they want to do so
 - The **reimbursement limitation** of a genericized brand based on the **generics price**, if patients refuse substitution¹
- If the generics penetration rate were **100%** of the exploited Directory², generics would account for **46%** of the total reimbursable retail market in volume...
- ... while the average within the **OECD** countries is **above 50%** (e.g. **85%** in the **UK** or **81%** in **Germany**)

In 2017, total expenditure for healthcare goods and services amounted to € 199.3 billion (of which ~47% from hospitals) and was mostly funded by the Social Security

Supply, consumption and funding of healthcare and medical goods

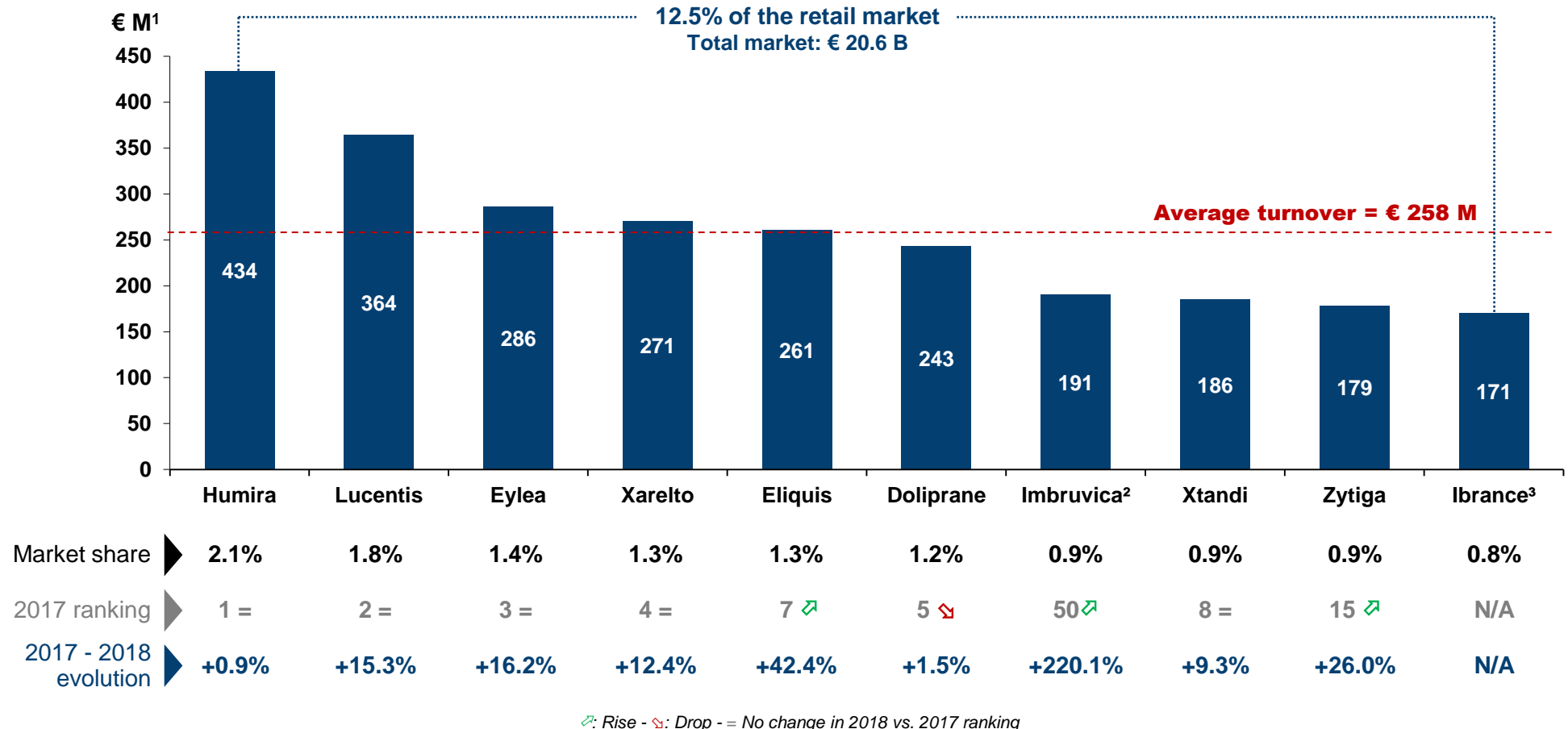


Sources: « Les dépenses de santé en 2017 - Résultats des comptes de la santé » (September 2018), DREES – Smart Pharma Consulting analysis

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

Humira remains the leader of the French retail market while Imbruvica entered the top 10 list, moving from the 50th in 2017 to the 7th position in 2018

Top 10 products in value – Retail sales (2018)

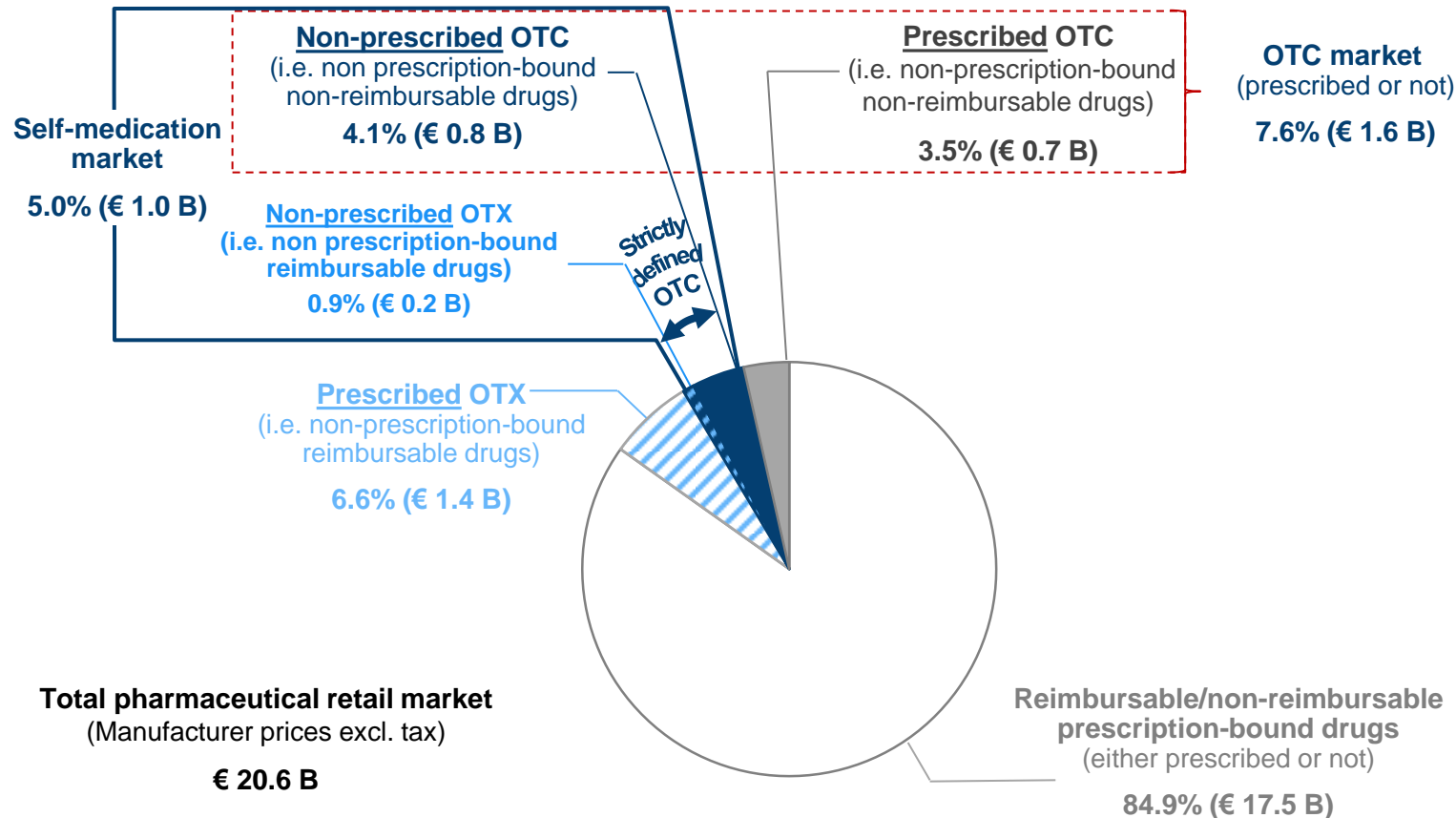


Sources: GERS – Smart Pharma Consulting analyses

¹ Constant ex-factory prices excluding rebates and taxes – ² Progressively transferred from the hospital to the retail market, since August 2017 – ³ Progressively transferred from the hospital to the retail market from March 2018

In 2018, the self-medication market accounted for 5.0% of the retail pharmaceutical market and included both reimbursable and non-reimbursable non-prescribed drugs

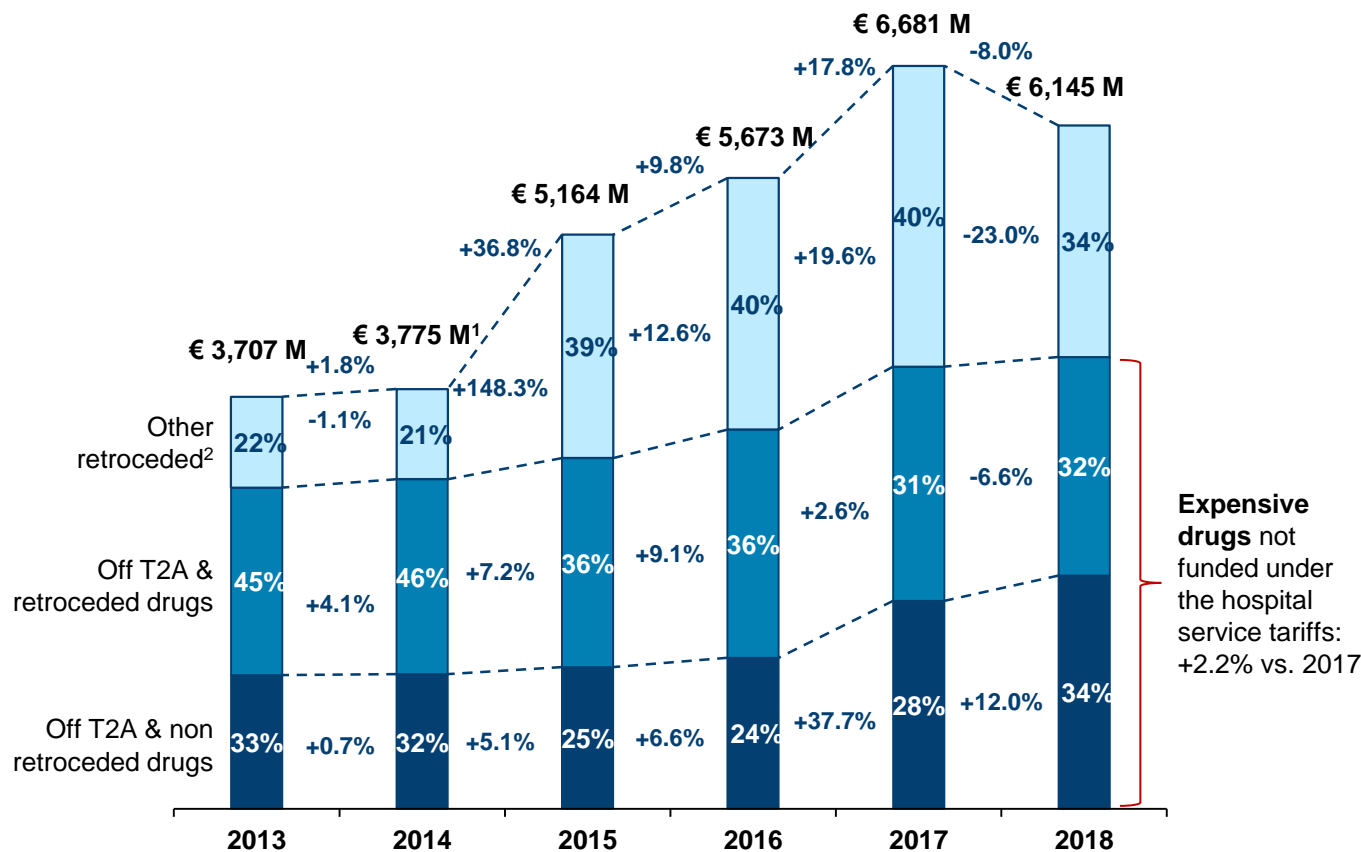
OTC market size and structure (2018)



- The strictly defined OTC market accounts for **82% of the self medication market**
- OTX or semi-ethical drugs (non-prescription-bound, reimbursed only if prescribed) are massively prescribed by physicians (sometimes on patient request), which limits the growth of the reconstituted self-medication sales

In 2018, the decrease of on top of T2A drugs sales vs. 2017 was mainly due to the transfer of classes of products (e.g. hepatitis C) from the hospital to the retail market

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

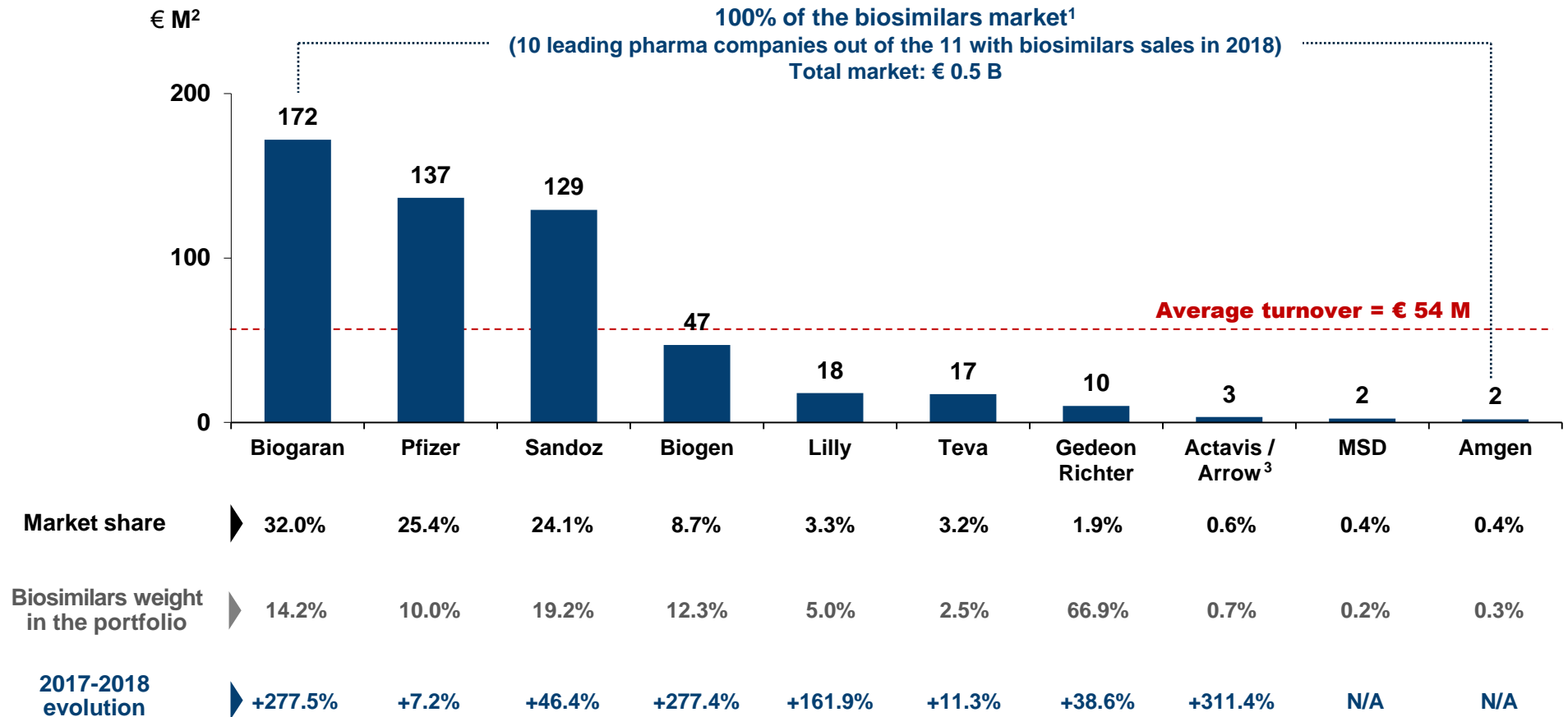


- In 2018, the **decrease** by **8.0%** of on-top of T2A drugs sales vs. 2017 was explained by the **transfer** of classes of drugs from the **hospital** to the **retail** market (e.g. **hepatitis C drugs**, whose transfer was decided on March 29th, 2018 and effective since April 2nd, 2018)
- In 2018,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

Drug	Therapeutic class	2018 sales³
Revlimid <i>Celgene</i>	Other antineoplastics	€ 266 M
Lovenox <i>Sanofi</i>	Fractionated heparins	€ 160 M
Epclusa <i>Gilead</i>	Hepatitis C antivirals	€ 153 M
Darzalex <i>J&J</i>	Monoclonal antibody antineoplastics	€ 147 M
Imnovid <i>Celgene</i>	Other antineoplastics	€ 142 M
Remicade <i>MSD</i>	Anti-TNF	€ 110 M

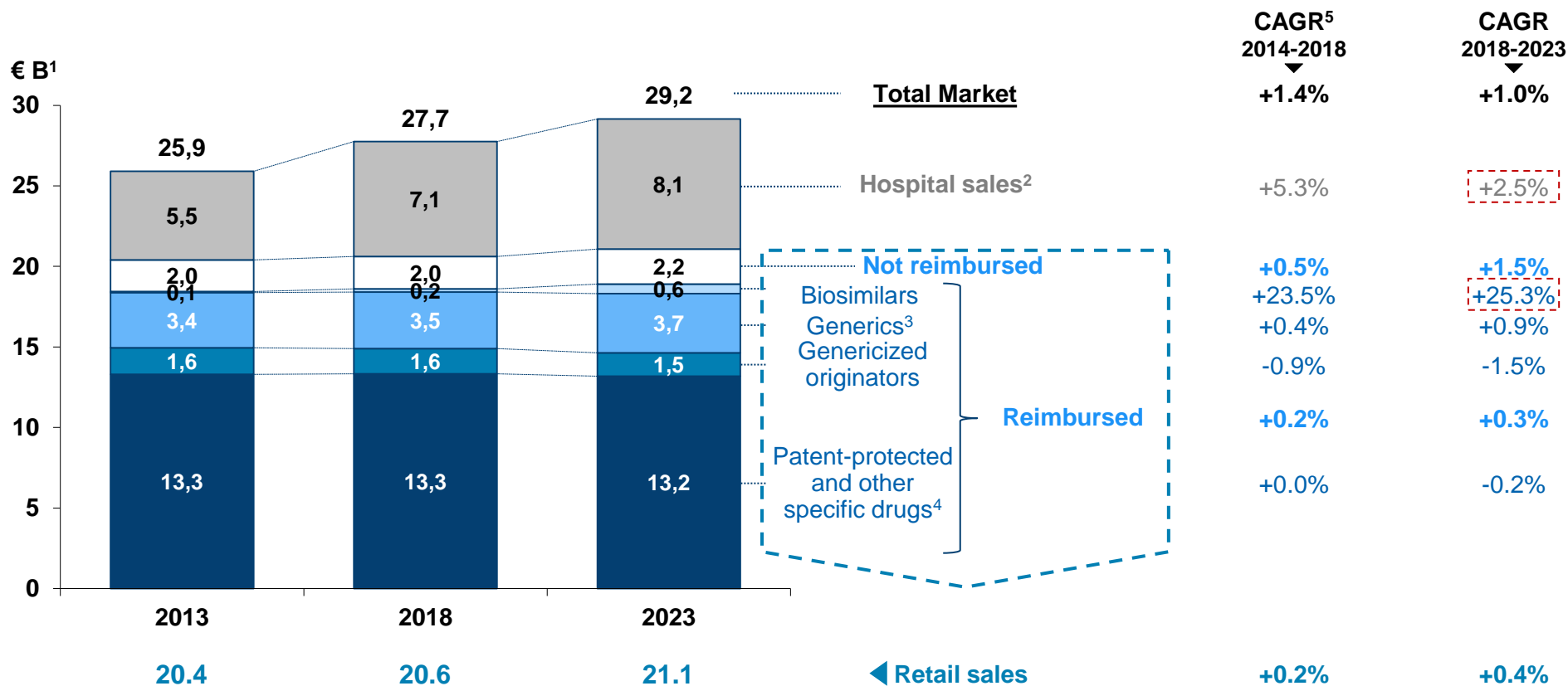
In 2018, Biogaran, Pfizer and Sandoz generated more than € 100 M sales and represented together ~82% of the French biosimilars market in value

Top 10 companies on the biosimilars market – In value¹ (2018)



By 2023, the French pharmaceutical market should be mainly driven by innovative hospital products and biosimilars

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

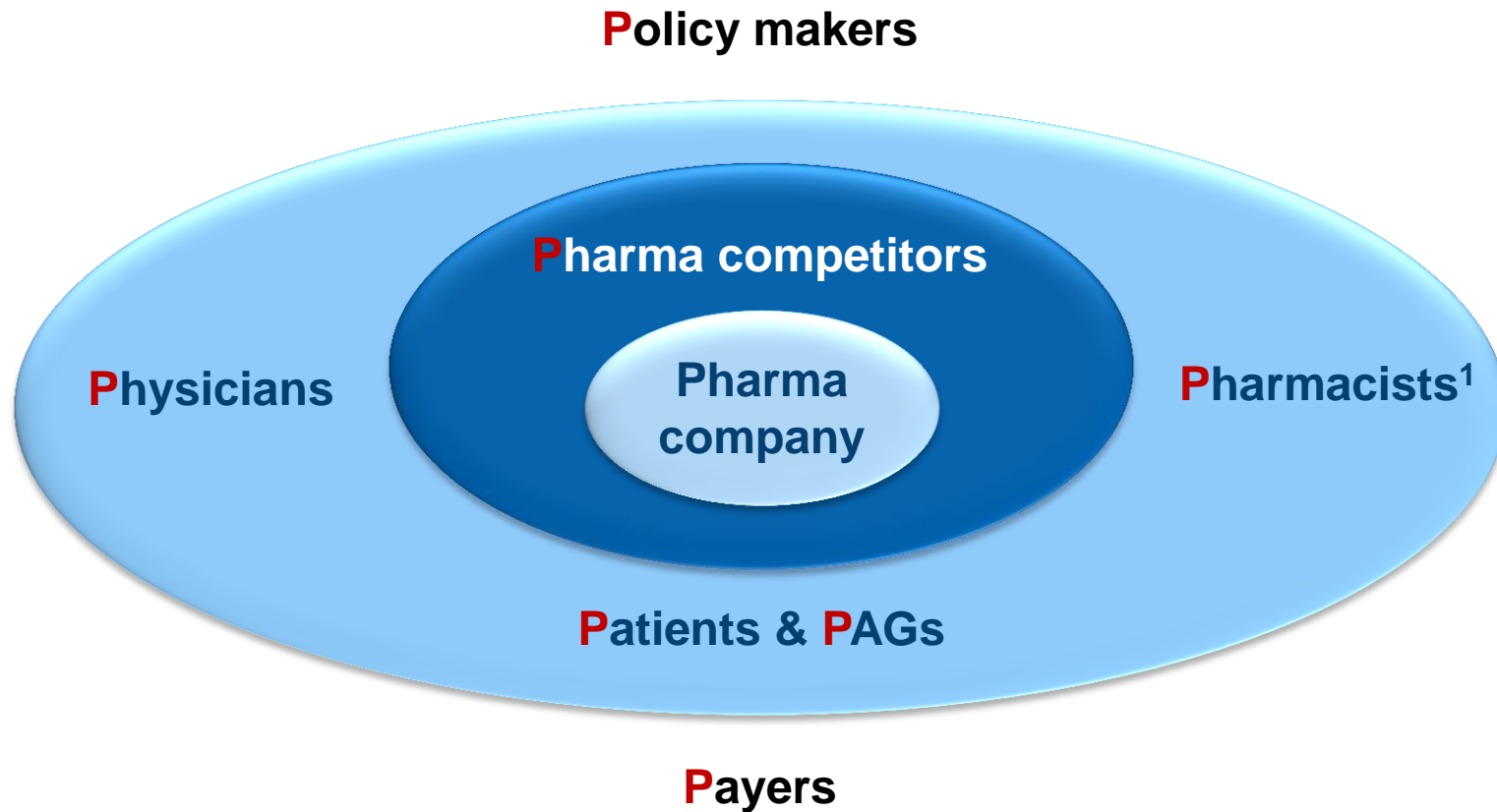


Sources: GERS dashboards – Smart Pharma Consulting estimates

¹ Constant ex-factory prices – ² Estimated rebated sales including hospital sales of biosimilars, products invoiced in addition of the hospitalization charges (on top of T2A) and reassigned medicine sales – ³ Reimbursable generics and quasi-generics – ⁴ Sales of drugs whose patents have not expired and of other specific products (calcium, sodium, potassium, paracetamol, etc.) – ⁵ Compound Annual Growth Rate

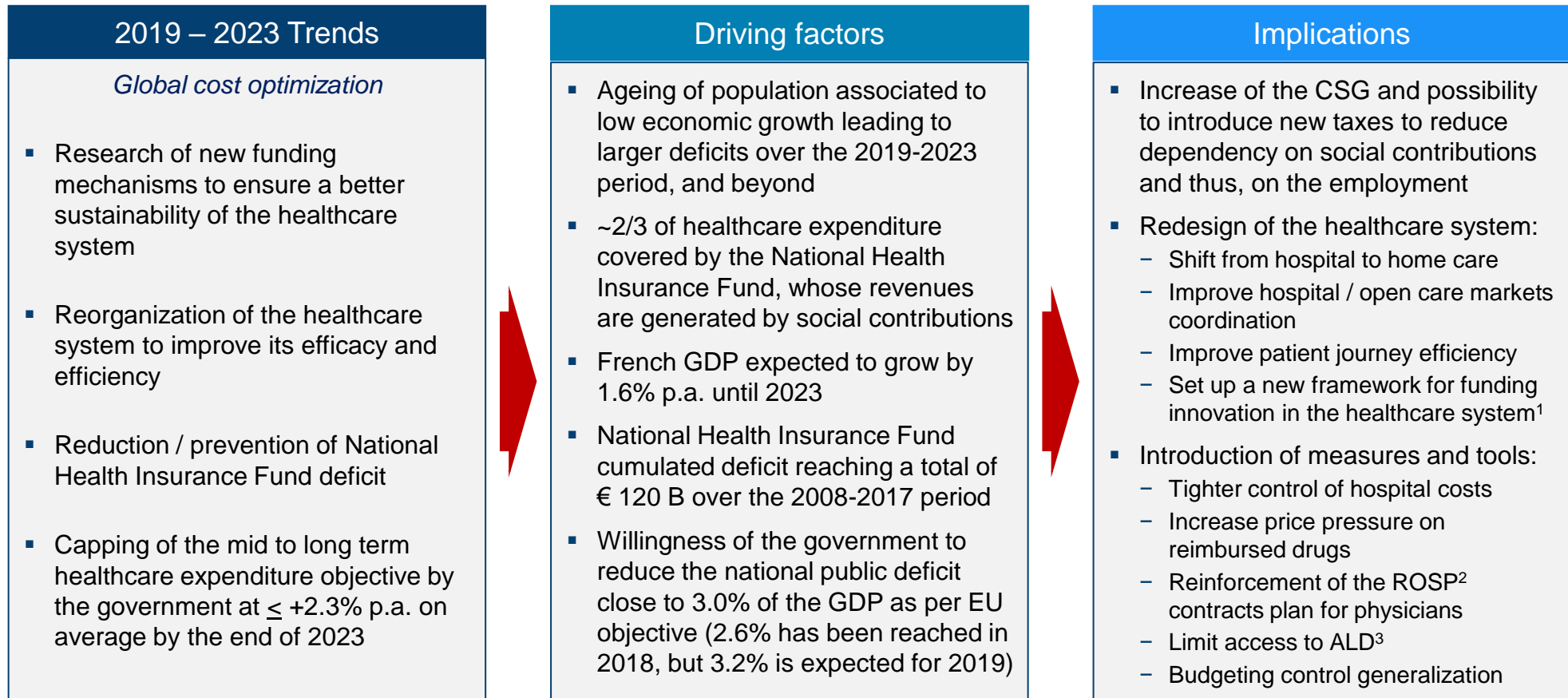
Pharmaceutical companies strategic priorities by 2023 will be linked with the behavior of the “7 Ps” stakeholders

7Ps



Policy makers & 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: Smart Pharma Consulting analyses

¹ As addressed in the Article 51 of the LFSS 2018 – ² Bonus program to encourage physicians to comply with “best prescribing practices” for a better efficacy/cost ratio – ³ 100% cost coverage for chronic and long-lasting diseases

Pharma companies must position their products, services and themselves to be perceived by Policy makers and Payers as offering superior value than competition

Strategic priorities induced by Policy makers & Payers behavioral trends

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 the 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 (whenever 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

Succeeding on the French Biosimilars Market



Smart Pharma
Consulting

**Everything you
wanted to know!**

Position Paper

June 2019

1, rue Houdart de Lamotte – 75015 Paris – France
Tel.: +33 6 11 96 33 78 - E-mail: jm.peny@smart-pharma.com – Website: www.smart-pharma.com

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

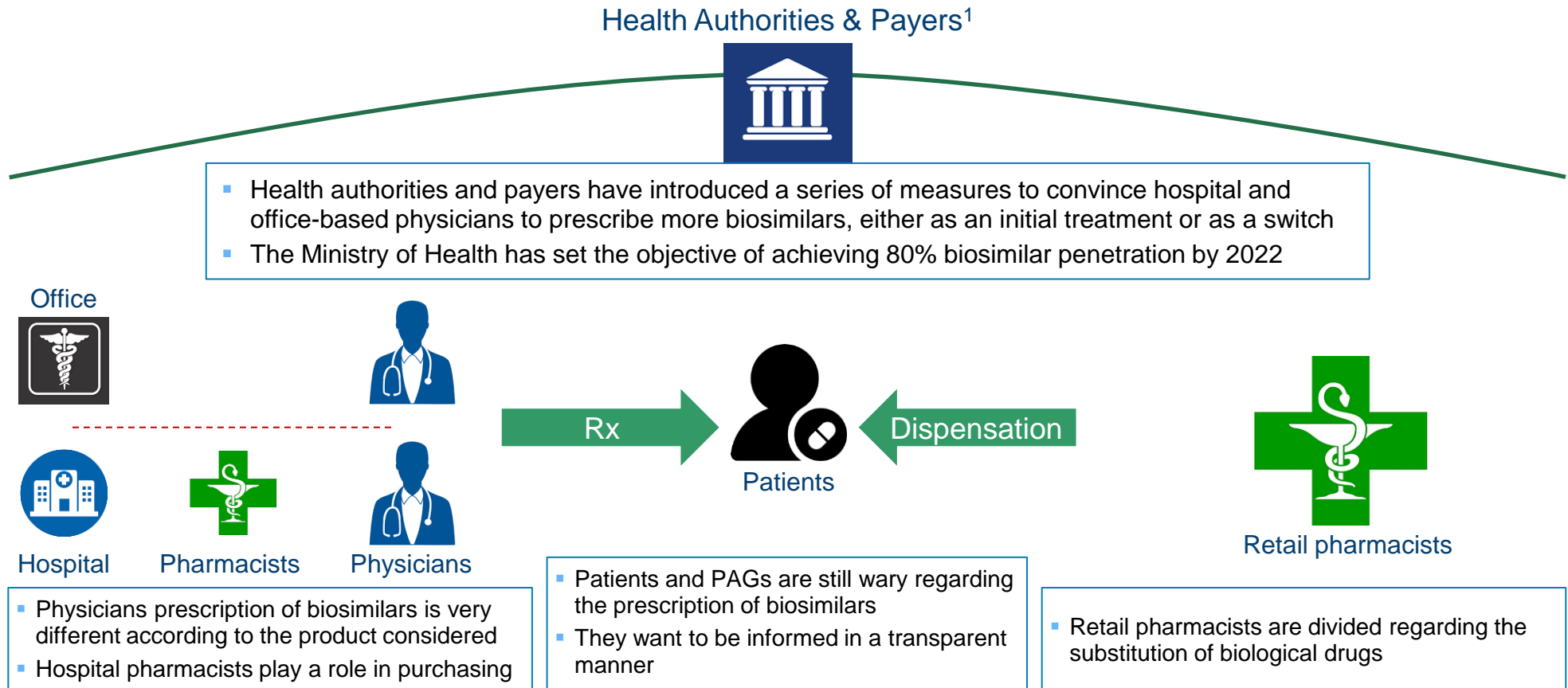
Context & objectives



- Sandoz, Teva or Hospira (Pfizer), which have pioneered the biosimilars market in France, have placed great hopes in its development
- However, 12 years down the road, the achievement of these precursors and of the followers can be regarded as somewhat below expectations
- **Smart Pharma Consulting**, which has developed a robust experience at analyzing and advising pharma companies on the biosimilars market, proposes to:
 1. Analyze the biosimilars market structure and dynamics
 2. Review the French regulatory environment
 3. Share insights regarding customers behaviors
 4. Evaluate the competitive landscape and the key success factors
 5. Estimate 2018 – 2023 market growth

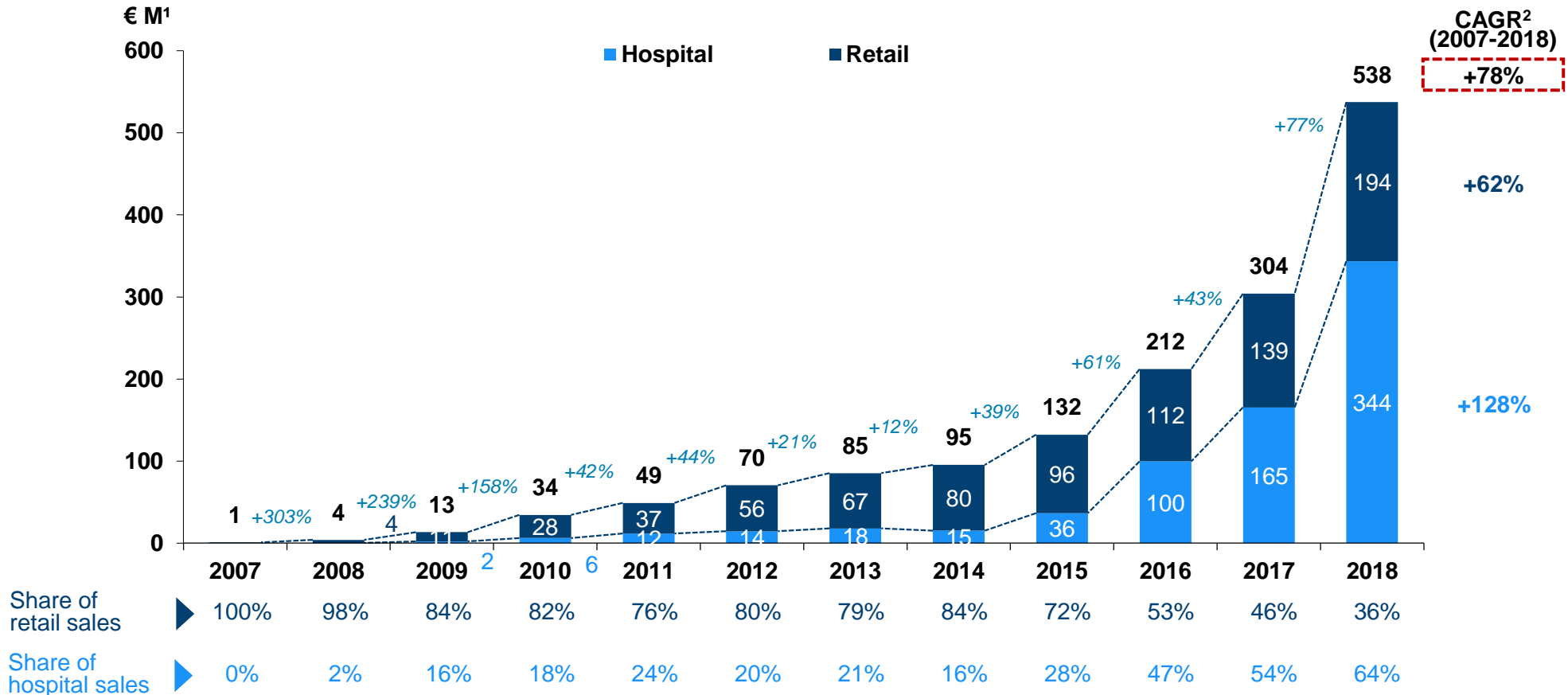
The biosimilars development on the French market is driven by the prescription of physicians who are encouraged by health authorities and certain hospital managers

Stakeholders involved in the French biosimilars market



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

Evolution of the biosimilars market (2007 – 2018)

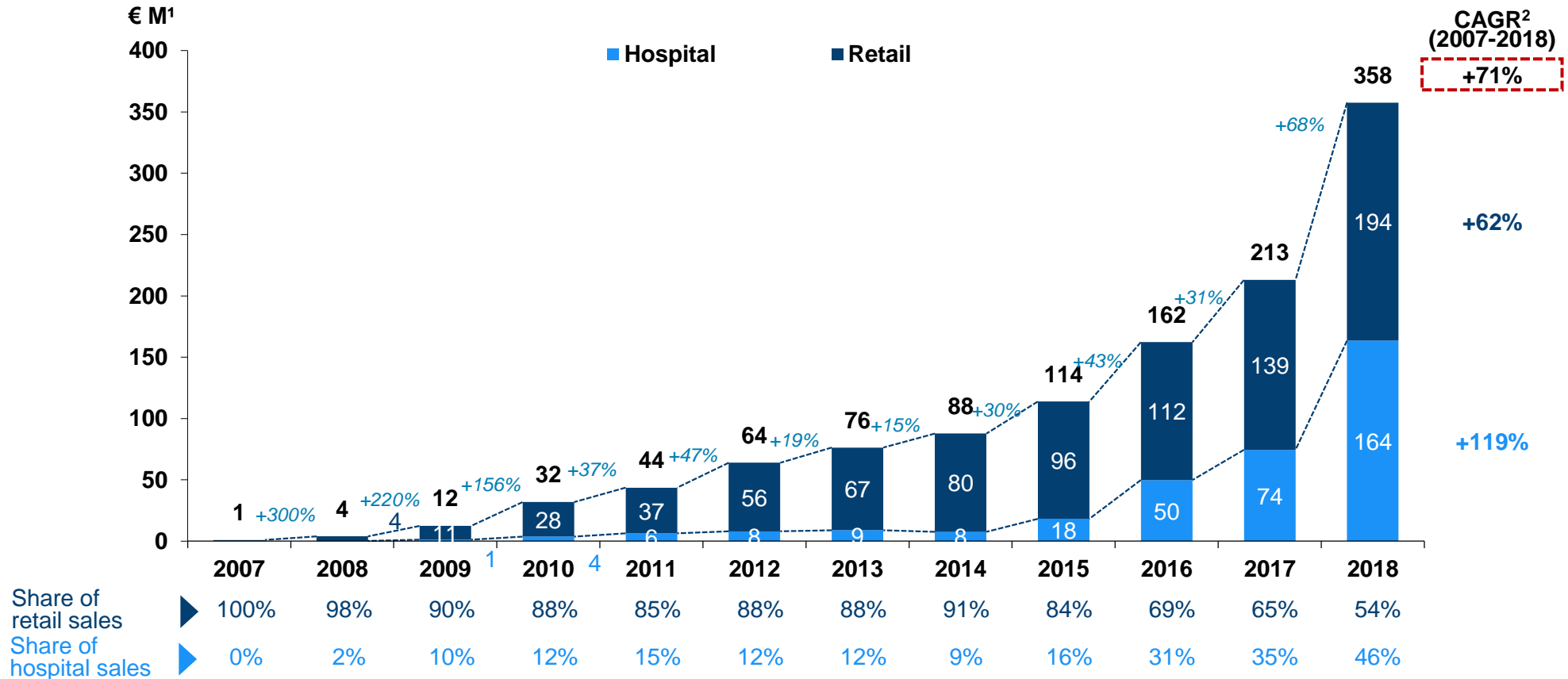


Sources: GERS – Smart Pharma Consulting analyses

¹ Ex-factory prices excluding rebates and taxes – ² Compound annual growth rate

When considering the rebates granted to hospitals on list prices, the 2018 biosimilars market reached € 358 M and the hospital sales are reduced to 46% of the total

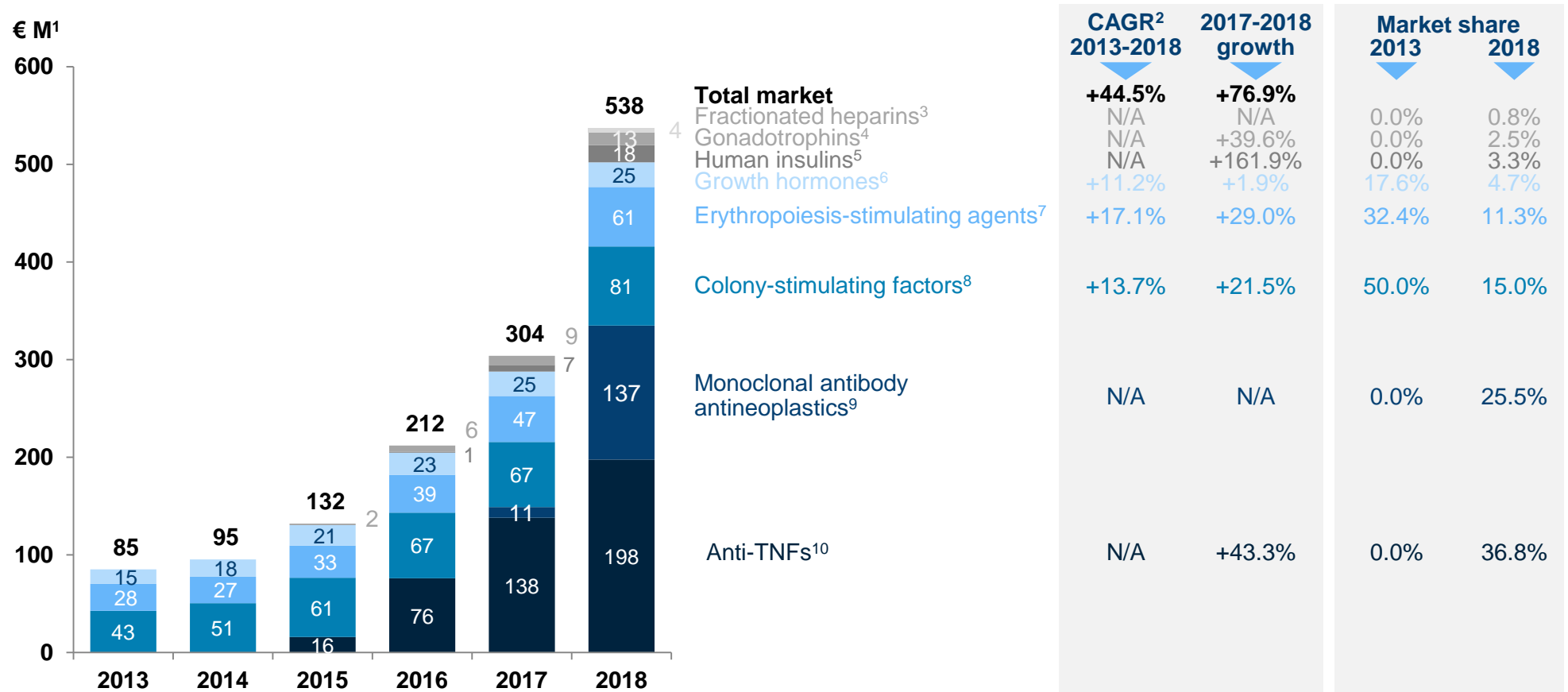
Evolution of the biosimilars market (2007 – 2018) – Net prices



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

In terms of therapeutic classes, anti-TNFs dominate the French biosimilars market, followed by monoclonal antibody antineoplastics and colony-stimulating factors

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



Sources: GERS – Smart Pharma Consulting analyses

¹ Ex-factory prices excluding rebates and taxes – ² Compound annual growth rate – ³ Enoxaparin sodium – ⁴ Follitropin alfa – ⁵ Insulin glargine – ⁶ Somatropin – ⁷ Epoetin – ⁸ Filgrastim and pegfilgrastim – ⁹ Rituximab and trastuzumab – ¹⁰ Adalimumab, etanercept and infliximab

With 3 biologic originators whose patent has expired, 7 biosimilars launched by 5 pharma companies, anti-TNF biosimilars sales reached € 198 M in 2018

Anti-TNF biosimilar drugs marketed in France (2018)

INN ¹ (Originator)	Product name	Pharma company	Launch date	Hospital sales ²	Retail sales ²	Total sales ²	Biosimilars penetration ³
Infliximab (Remicade, MSD)	▪ Inflectra	▪ Pfizer	▪ Feb. 2015	€ 95.8 M	€ 0.0 M	€ 95.8 M	69.6%
	▪ Remsima	▪ Biogaran	▪ Feb. 2015	€ 52.0 M	€ 0.0 M	€ 52.0 M	
	▪ Flixabi	▪ Biogen	▪ Mar. 2017	€ 27.6 M	€ 0.0 M	€ 27.6 M	
	3 products	3 companies		€ 175.5 M	€ 0.0 M	€ 175.5 M	
Etanercept (Enbrel, Pfizer)	▪ Benepali	▪ Biogen	▪ Oct. 2016	€ 0.1 M	€ 19.0 M	€ 19.1 M	20.3%
	▪ Erelzi	▪ Sandoz	▪ Nov. 2017	€ 0.0 M	€ 2.2 M	€ 2.2 M	
	2 products	2 companies		€ 0.1 M	€ 21.2 M	€ 21.3 M	
Adalimumab (Humira, AbbVie)	▪ Amgevita	▪ Amgen	▪ Oct. 2018	€ 0.0 M	€ 0.5 M	€ 0.5 M	2.3%
	▪ Imraldi	▪ Biogen	▪ Oct. 2018	€ 0.0 M	€ 0.3 M	€ 0.3 M	
	2 products	2 companies ⁴		€ 0.0 M	€ 0.8 M	€ 0.8 M	
Total	7 products	5 companies		€ 175.6 M	€ 22.0 M	€ 197.6 M	

Sources: GERS – Smart Pharma Consulting analyses

¹ International Non-propriety Name – ² Ex-factory prices excluding rebates and taxes – ³ Biosimilar penetration in volume in December 2018 – ⁴ As of June 2019, two more biosimilars have entered the market: Hulio (Mylan) and Hyrimoz (Sandoz). An additional biosimilar, Idacio (Fresenius Kabi) is expected in the coming months

With 2 biologic drugs from Roche whose patent has expired, 5 biosimilars launched by 4 companies, rituximab & trastuzumab biosimilars sales reached € 137 M in 2018

Monoclonal antibody antineoplastics biosimilar drugs marketed in France (2018)

INN ¹ (Originator)	Product name	Pharma company	Launch date	Hospital sales ²	Retail sales ²	Total sales ²	Biosimilars penetration ³
Rituximab (MabThera, Roche)	▪ Truxima	▪ Biogaran	▪ Sep. 2017	€ 104.8 M	€ 0.0 M	€ 104.8 M	82.2%
	▪ Rixathon	▪ Sandoz	▪ Jan. 2018	€ 18.1 M	€ 0.0 M	€ 18.1 M	
	2 products	2 companies		€ 122.8 M	€ 0.0 M	€ 122.8 M	
Trastuzumab (Herceptin, Roche)	▪ Herzuma	▪ Biogaran	▪ Jul. 2018	€ 10.7 M	€ 0.0 M	€ 10.7 M	62.3%
	▪ Ontruzant	▪ MSD	▪ Sep. 2018	€ 2.4 M	€ 0.0 M	€ 2.4 M	
	▪ Kanjinti	▪ Amgen	▪ Aug. 2018	€ 1.4 M	€ 0.0 M	€ 1.4 M	
	3 products	3 companies		€ 14.5 M	€ 0.0 M	€ 14.5 M	
Total	5 products	4 companies		€ 137.3 M	€ 0.0 M	€ 137.3 M	

Sources: GERS – Smart Pharma Consulting analyses

¹ International Non-propriety Name – ² Ex-factory prices excluding rebates and taxes –

³ Biosimilar penetration in volume in December 2018

With 2 biologic drugs from Amgen whose patent has expired, 5 biosimilars launched by 5 pharma companies, G-CSF biosimilars sales reached € 81 M in 2018

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

INN ¹ (Originator)	Product name	Pharma company	Launch date	Hospital sales ²	Retail sales ²	Total sales ²	Biosimilars penetration ³
Filgrastim (Neupogen, Amgen)	▪ Zarzio	▪ Sandoz	▪ Oct. 2009	€ 10.7 M	€ 36.4 M	€ 47.1 M	94.1%
	▪ Nivestim	▪ Pfizer	▪ Jun. 2011	€ 4.9 M	€ 18.6 M	€ 23.5 M	
	▪ Tevagrastim	▪ Teva	▪ Mar. 2010	€ 1.5 M	€ 5.1 M	€ 6.7 M	
	▪ Accofil	▪ Arrow	▪ Feb. 2016	€ 2.6 M	€ 0.8 M	€ 3.3 M	
	4 products	4 companies		€ 19.7 M	€ 60.9 M	€ 80.6 M	
Pegfilgrastim (Neulasta, Amgen)	▪ Pelgraz	▪ Accord Healthcare	▪ Nov. 2018	€ 0.0 M	€ 0.2 M	€ 0.2 M	2.5%
	1 product	1 company		€ 0.0 M	€ 0.2 M	€ 0.2 M	
Total	5 products	5 companies		€ 19.7 M	€ 61.1 M	€ 80.8 M	

Sources: GERS – Smart Pharma Consulting analyses

¹ International Non-propriety Name – ² Ex-factory prices excluding rebates and taxes –

³ Biosimilar penetration in volume in December 2018

Epoetin and somatropin biosimilars, whose first products were launched ~10 years ago, reached penetration rates of almost 50% in December 2018

Other biosimilar drugs marketed in France (2018)

EPHRA 4 therapeutic class	INN ¹ (Originator)	Product name	Pharma company	Launch date	Hospital sales ²	Retail sales ²	Total sales ²	Biosimilars penetration ³
Erythropoiesis- stimulating agents	Epoetin (Eprex, Janssen)	▪ Binocrit	▪ Sandoz	▪ Jul. 2008	€ 7.1 M	€ 29.3 M	€ 36.4 M	48.2%
		▪ Retacrit	▪ Pfizer	▪ Mar. 2009	€ 0.8 M	€ 16.5 M	€ 17.3 M	
		▪ Eporatio ⁴	▪ Teva	▪ May 2010	€ 0.6 M	€ 6.6 M	€ 7.2 M	
		3 products	3 companies		€ 8.5 M	€ 52.4 M	€ 60.9 M	
Growth hormones	Somatropin (Genotonorm, Pfizer)	▪ Omnitrope	▪ Sandoz	▪ May 2007	€ 0.0 M	€ 25.4 M	€ 25.4 M	49.3%
		1 product	1 company		€ 0.0 M	€ 25.4 M	€ 25.4 M	
Human insulins	Insulin glargine (Lantus, Sanofi)	▪ Abasaglar	▪ Lilly	▪ Jan. 2016	€ 2.3 M	€ 15.5 M	€ 17.8 M	17.8%
		1 product	1 company		€ 2.3 M	€ 15.5 M	€ 17.8 M	
Gonadotrophins	Follitropin alfa (Gonal-F, Merck)	▪ Bemfola	▪ Gedeon Richter	▪ May 2015	€ 0.0 M	€ 10.0 M	€ 10.0 M	48.9%
		▪ Ovaleap	▪ Theramex	▪ May 2016	€ 0.0 M	€ 3.2 M	€ 3.2 M	
		2 products	2 companies		€ 0.0 M	€ 13.2 M	€ 13.2 M	
Fractionated heparins	Enoxaparin sodium (Lovenox, Sanofi)	▪ Enoxaparine Crusia	Biogaran	▪ Sept. 2018	€ 0.1 M	€ 4.4 M	€ 4.5 M	8.0%
		1 product	1 company		€ 0.1 M	€ 4.4 M	€ 4.5 M	

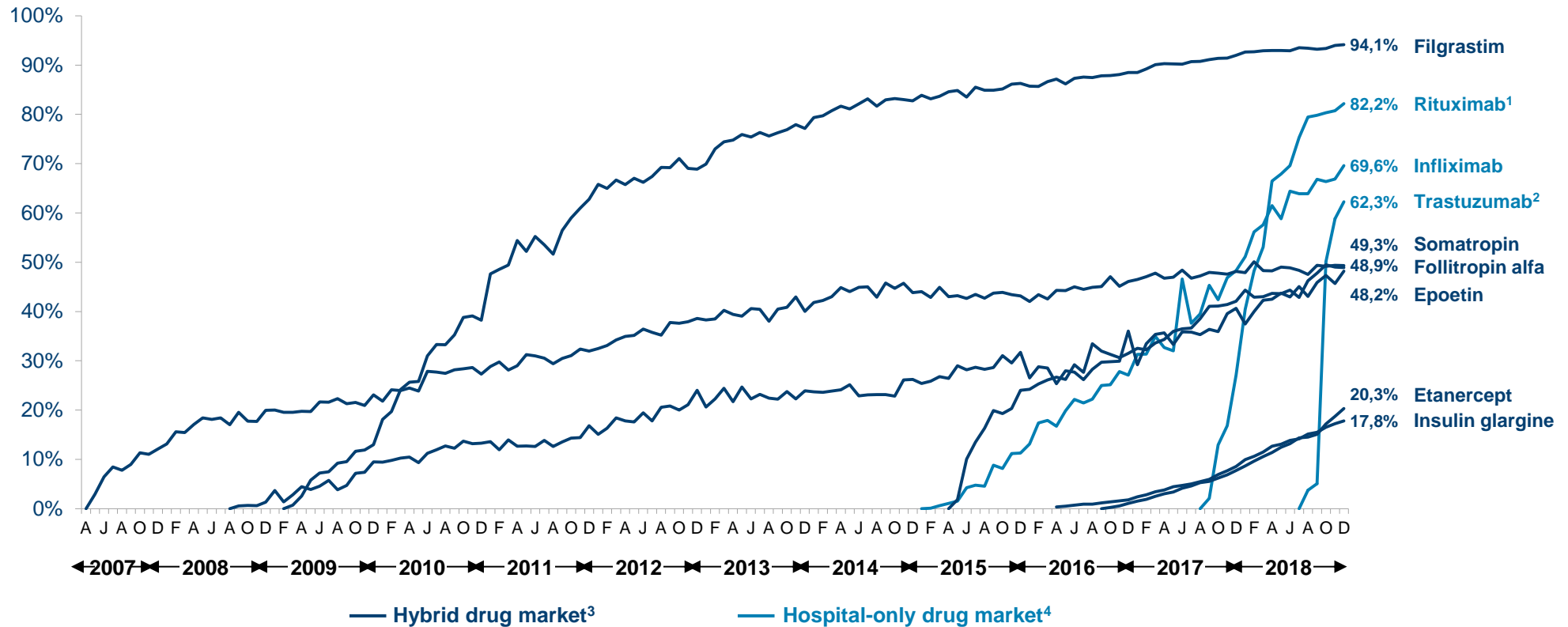
Sources: GERS – Smart Pharma Consulting analyses

¹ International Non-propriety Name – ² Ex-factory prices excluding rebates and taxes – ³ Biosimilar penetration in volume in December 2018 – ⁴ Eporatio is not a biosimilar per se but rather a “me-too” product

Biosimilar penetration is faster and faster, notably in the hospital market where it ranged from ~62% (for trastuzumab) to ~82% (for rituximab) in December 2018

Biosimilars market penetration

Biosimilars market penetration
(as a % sales in volume)



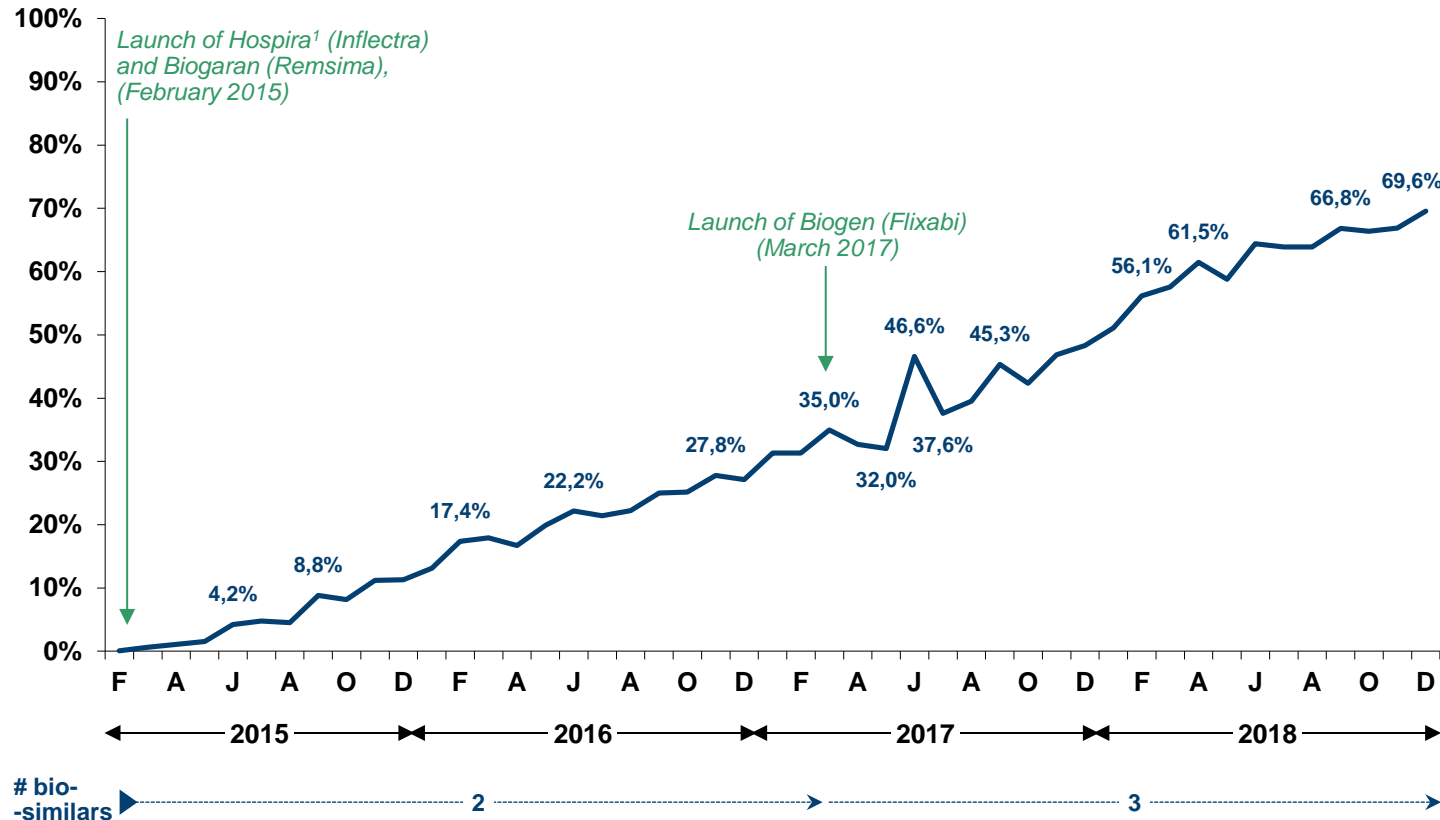
Sources: GERS – Smart Pharma Consulting analyses

¹ Excluding the 1,400 mg subcutaneous form, that is not yet subject to biosimilars competition – ² Excluding the 600 mg subcutaneous form, that is not yet subject to biosimilars competition – ³ Products bought and/or delivered at hospitals and retail pharmacies – ⁴ Products exclusively bought and delivered at hospitals

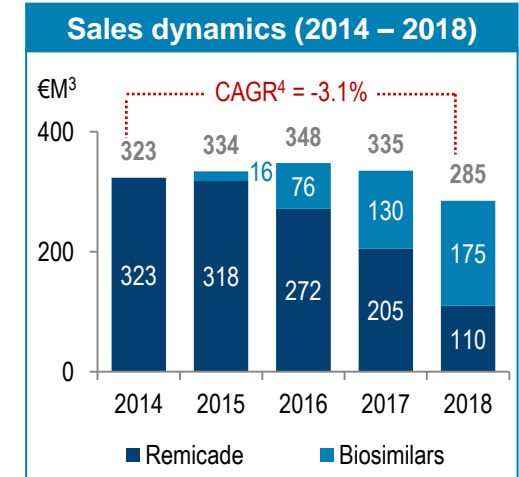
Infliximab biosimilars penetration reached ~70% of the market in volume, ~4 years after biosimilar entry, despite MSD competitive price offering

Penetration rate in volume – Infliximab case study

Biosimilars penetration as a % of infliximab sales in standard units



Comments	
Originator	Remicade (MSD)
Status	On-top of T2A ² biologic drug
EPHMA class	Anti-TNFs (L04B)
Indications	Ulcerative colitis, Crohn's disease, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and psoriasis



Sources: GERS – Thériaque – Smart Pharma Consulting analyses

¹ Acquired by Pfizer in September 2015 – ² Activity-based costing – ³ Ex-factory price, excluding VAT and rebates – ⁴ Compound annual growth rate

The French biosimilars market is split in two different segments that require, from pharma companies, different strategies, tactics and organizational models to succeed

The biosimilars market segments

Hospital-only market segment		Hybrid market segment
<ul style="list-style-type: none"> Prescribed, purchased and delivered at hospitals (e.g. infliximab, rituximab, trastuzumab) 	Definition	<ul style="list-style-type: none"> Prescribed by hospital and/or office-based specialists, purchased and delivered by hospital and retail pharmacies (e.g. epoetin, filgrastim) or retail pharmacies only (e.g. follitropin alfa, somatropin)
<ul style="list-style-type: none"> Free pricing for drugs included in T2A system¹ Responsibility tariff set by the CEPS² for drugs on-top of the T2A list³ (e.g. infliximab, rituximab) 	Pricing	<ul style="list-style-type: none"> Ex-factory price set by the CEPS initially at -30% or -40% below the original biologic on the hospital and the retail market segments, respectively
<ul style="list-style-type: none"> Mainly purchased through tenders and/or to a lower extent through negotiated agreements Possibility to grant rebates to hospitals Strong price pressure 	Purchasing	<ul style="list-style-type: none"> The level of rebates to retail pharmacies is limited to a maximum of 2.5% of the ex-factory price which is in general granted by wholesalers⁴ Limited price pressure on retail sales
<ul style="list-style-type: none"> Medical activity carried out by MSLs to reassure prescribers about the quality of the biosimilars Key account management activity carried out by KAMs to win tenders and set up a follow up plan 	Medico-marketing activities	<ul style="list-style-type: none"> Medical activity carried out by MSLs to reassure prescribers about the quality of the biosimilars Promotional activity carried out by marketers and medical reps to be prescribed to in- and out-patients
<ul style="list-style-type: none"> Market size 2018: € 164 M (net price) Market growth 2007 – 2018: + 119% (net sales) Leading players profitability: medium to high 	Market size & profit level	<ul style="list-style-type: none"> Market size 2018: € 194 M (net price = price list) Market growth 2007 – 2018: + 62% (net sales) Leading players profitability: high

Sources: Smart Pharma Consulting analyses

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

Substitution of biosimilars by retail pharmacists, at treatment initiation, is legal since 2013, but the absence of the corresponding decree does not allow its implementation

Regulations specific to biosimilars

Biosimilar drugs ¹	<div data-bbox="801 396 1048 544">Biosimilar register</div> <ul style="list-style-type: none"> The ANSM² has created in 2017 similar biologic groups, each of them defined by a reference biologic and its corresponding biosimilars, listed by brand name
<ul style="list-style-type: none"> A biosimilar drug is any biological drug that has the same qualitative and quantitative composition of active substance and the same pharmaceutical form as a biological originator... ... but does not fulfill the conditions for being regarded as a generic due to differences related in particular to raw material variability or manufacturing processes requiring the achievement of additional preclinical and clinical data under regulatory conditions... ... demonstrating that the biosimilar: <ul style="list-style-type: none"> Is similar to the biological originator Does not differ significantly from the biological originator in terms of quality, efficacy and safety 	<div data-bbox="801 544 1048 1086">Biosimilar substitution right</div> <ul style="list-style-type: none"> France was the first European country to allow the substitution of biosimilars, in December 2013 Biosimilars substitution is only permitted if: <ul style="list-style-type: none"> A new treatment is started Within the same similar biologic group The prescriber has not explicitly prohibited, in writing, the substitution of the prescribed drug The pharmacist has informed the prescriber... ... and recorded the details of biosimilar dispensed In the absence of a decree defining the conditions of substitution, the law has not yet been implemented
	<div data-bbox="801 1086 1048 1240">Inter-changeability</div> <ul style="list-style-type: none"> The ANSM has specified in May 2016 that inter-changeability was possible between biologic drugs belonging to the same similar biologic group

The health authorities are strongly determined to accelerate the penetration of biosimilars, but remain relatively cautious to avoid any potential public health issue

Health authorities measures to boost biosimilars

LFSS 2018 – Focus on the CAQES

- Since January 2018, contracts between hospitals, health regional agencies and health insurance named CAQES¹, have set prescription targets for biosimilars

Objective

- Achieve **70%** penetration of hospital biosimilars in units, at **national level**²

Implementation

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

2017 – Ministerial Order

- The DGOS³, DSS⁴, DGS⁵ and the UNCAM⁶ published an order on October 12th, 2017 to require the Regional Health Agencies (ARS) to promote the use of biosimilar drugs
- As a result, ARS are invited to promote the use of biosimilars by:
 - Informing patients
 - Harmonizing prescribers practices in favor of biosimilars
 - Helping hospitals organize tenders as soon as biosimilars are on the market
 - Developing financial tools to measure the savings related to biosimilars
- The DGOS has informed that physicians are authorized to switch one biological drug by another similar one during a treatment

LFSS 2018 – Article 51

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

Objective

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

Implementation

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

ROSP

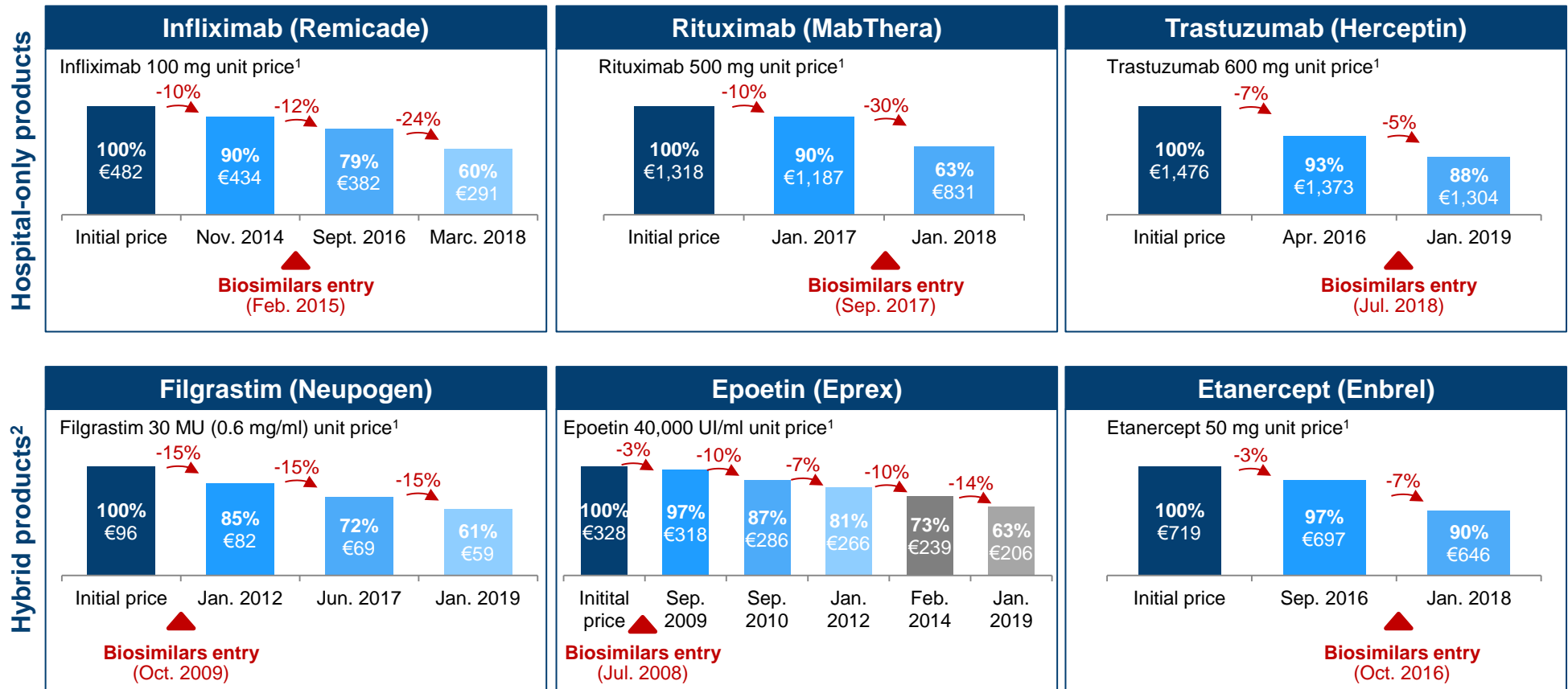
- This bonus program, which encourages physicians to comply with “best prescribing practices” for a better efficacy/cost ratio, includes, since 2017, the prescription of the insulin glargine biosimilar

Sources: Decree related to CAQES and setting quality and efficiency reference objectives – Smart Pharma Consulting analyses

¹ CAQES: contract for healthcare quality and efficiency enhancement – ² In December 2017, the government has set the global (hospital and retail markets) objective of 80% biosimilar penetration by 2022 – ³ Directorate of Health Care Supply – ⁴ Directorate of Social Security – ⁵ Directorate General for Health – ⁶ National Union of Health Insurance Funds – ⁷ Adalimumab has entered in the scope of the experiment in the second quarter 2019

Excepted for trastuzumab and etanercept, whose first biosimilars were launched in 2018 and 2016 respectively, the CEPS dropped all reference prices by ~40%

Historical imposed price cuts over time



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

¹ Ex-factory price per standard unit, excluding rebates and taxes –
² Products with sales at hospital levels and retail pharmacies

Biosimilars prices on the hospital market are either free or set by the drug pricing committee (CEPS), while on the ambulatory market they are always regulated

Biosimilars price regulation – New Health Authorities Doctrine



Hospital market segment

- If the reference biological drug is **included in the T2A** (activity-based costing system), thus its price, as well as its corresponding biosimilars ones, will be **unregulated**
- If the reference biological drug is on:
 - **The top of T2A hospital drug list¹** or
 - **The reassigned drug list²**

the CEPS (drug pricing committee) applies the following pricing principles, when the first biosimilar enters the market:

- A 30% price cut for the originator and its biosimilars
- 24 months and 48 months later, 10% to 30% additional price cuts depending on difference observed between actual net prices and prices set by the CEPS

Ambulatory market segment

- **At the entry date of biosimilars:**
 - The CEPS sets the price of biosimilars **40% below** the price of the originator
 - The originator is imposed a price cut of **20%**
 - **24 months and 42 months after the entry of the first biosimilar:**
 - Additional price cuts aimed at **price convergence...**
 - ... and depending on the respective **market shares** of the originator and of its biosimilars
- will be imposed



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

¹This list includes expensive products which are funded on top of the hospital service tariffs (hospital budget) to improve patients access to innovation – ² These products, which are on the retrocession list, can be sold to outpatients by the hospital pharmacies and, in such a case, are funded by the National Health Insurance Fund

Cost containment policies tend to make hospital prescribers increasingly concerned about costs induced by their prescriptions, providing opportunities for biosimilars

Biosimilars and cost of hospital prescriptions

Drugs dispensed at hospitals

- Since 2007, hospital expenditures are covered by the National Health Insurance Fund according to their activity level, based on a fixed fee-for-service model, called T2A¹
- As a result, hospitals have a strong incentive to pay the lowest price, as possible, for drugs and for the other goods they purchase, to achieve a balanced budget
- For drugs on “the top of T2A” and/or on the reassigned list, hospitals are reimbursed by the National Health Insurance Fund, at the reference price set by the CEPS²
- However, hospitals may obtain a lower price and, in such a case, the saving will be equitably distributed between hospitals and the National Health Insurance Fund

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

Drugs dispensed at retail pharmacies

- The article 47 of the Social Security Act for 2010 introduced a new measure to contain the cost of drugs dispensed in retail pharmacies, but prescribed at hospitals, as this cost was increasing much faster than that related to primary care prescriptions
- This measure sets an annual maximum growth rate (+4.0% for 2018 and +3.3% for 2019) of drug expenditure related to hospital prescriptions that are bought at retail pharmacies by patients
- If exceeded, the ARS⁴ may place the offending hospital under its supervision to compel it to improve prescribing practices, and may possibly demand financial penalties

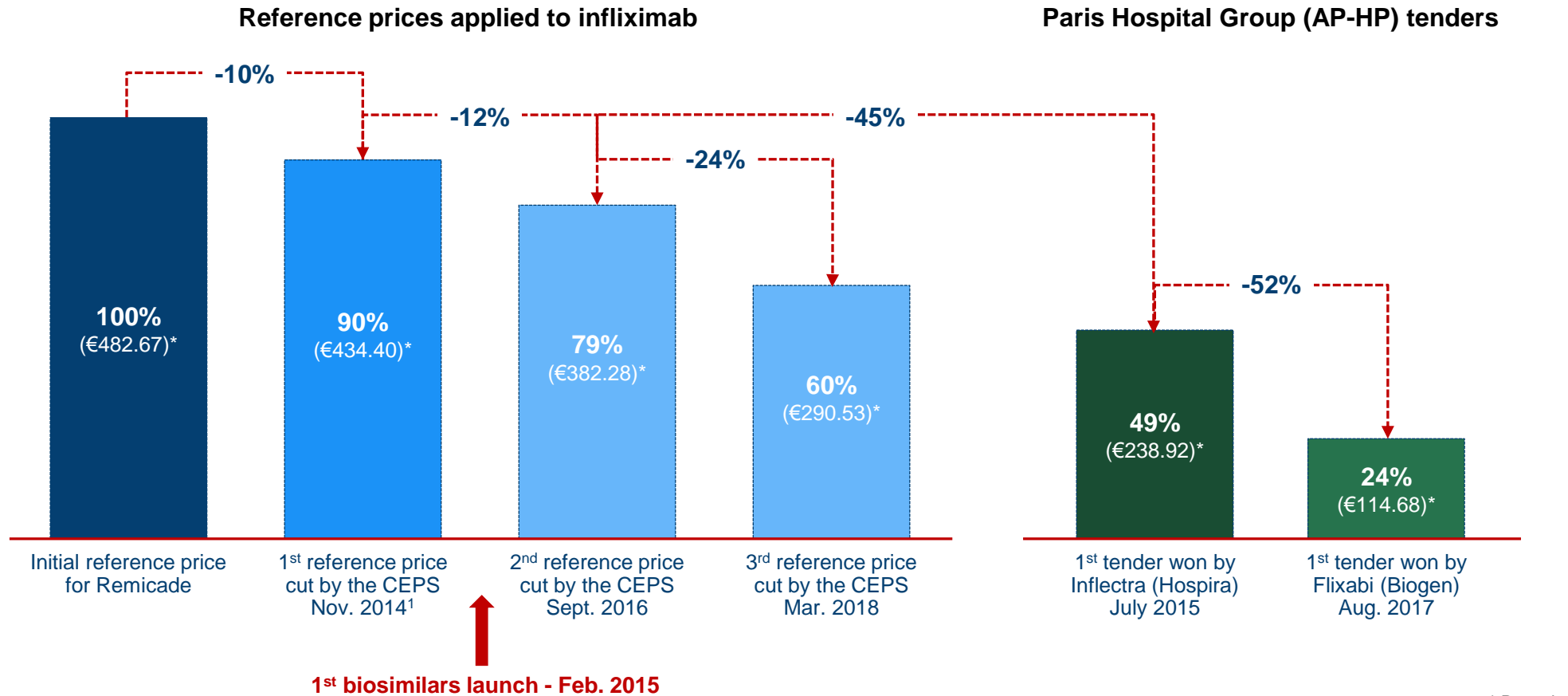
Prescription of biosimilars may help better control the cost evolution of drugs prescribed in hospital and dispensed in retail pharmacies

Sources: www.sante.gouv.fr/tarification-a-l-activite.html – Article 47, “LFSS 2010” Official Gazette, (December 27th, 2009) – Smart Pharma Consulting analyses

¹ Tarification à l'activité – ² Drug pricing committee – ³ Salaries account for ~70%, general & administrative expenses for ~18% and medical devices for ~6% – ⁴ Regional health agency

2.5 years after biosimilars entry, the net price of infliximab (ex-factory price minus hospital rebates) has been reduced by ~76%

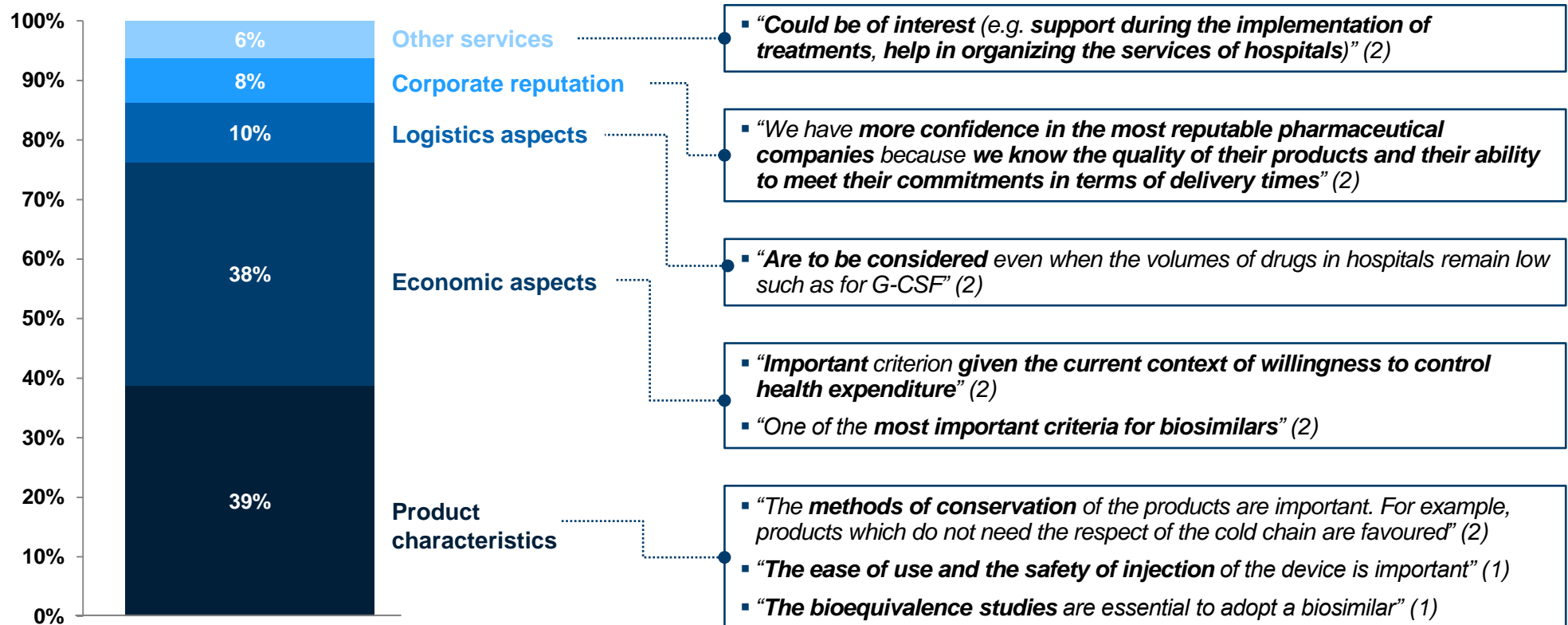
Hospital pricing evolution – Infliximab case study



The main criteria that will determine biosimilars listing in hospitals are product characteristics and economic aspects according to this pilot study

Listing procedures and protocols in hospitals

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



(X): Number of quotes

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

HCPs would adopt biosimilars provided their bioequivalence to the originator is proven and their pricing generates savings

Expectations from HCPs for biosimilars

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



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

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



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

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

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

Number of respondents: 10

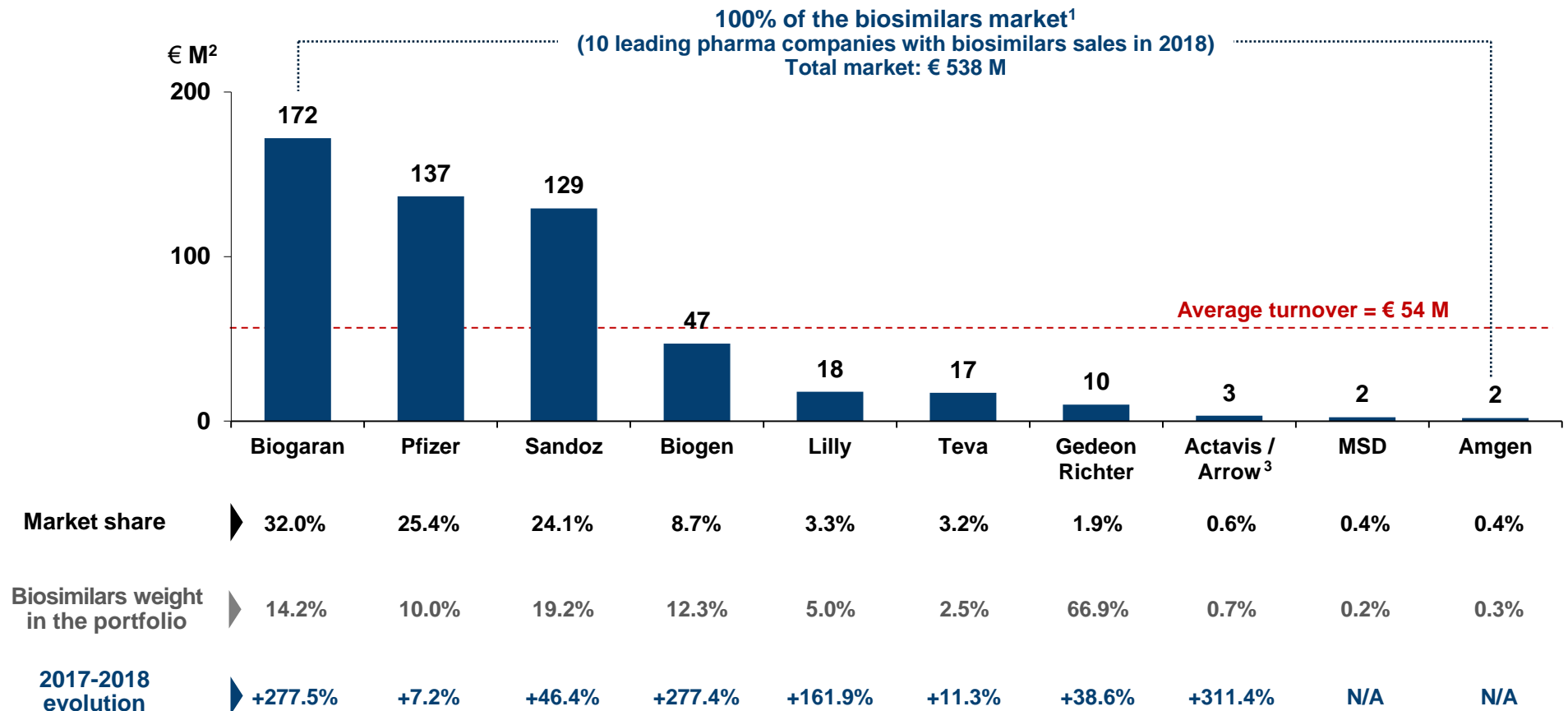
(X): Number of quotes

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

¹ Contract for the improvement of quality and efficiency of care – ² Hospital network regrouping the 18 regional centers for the fight against cancer (CRLCC) entirely dedicated to oncology and including a national purchasing unit

In 2018, Biogaran, Pfizer and Sandoz generated individually more than € 100 M sales and represented together ~82% of the French biosimilars market in value terms

Top 10 companies on the biosimilars market – In value¹ (2018)

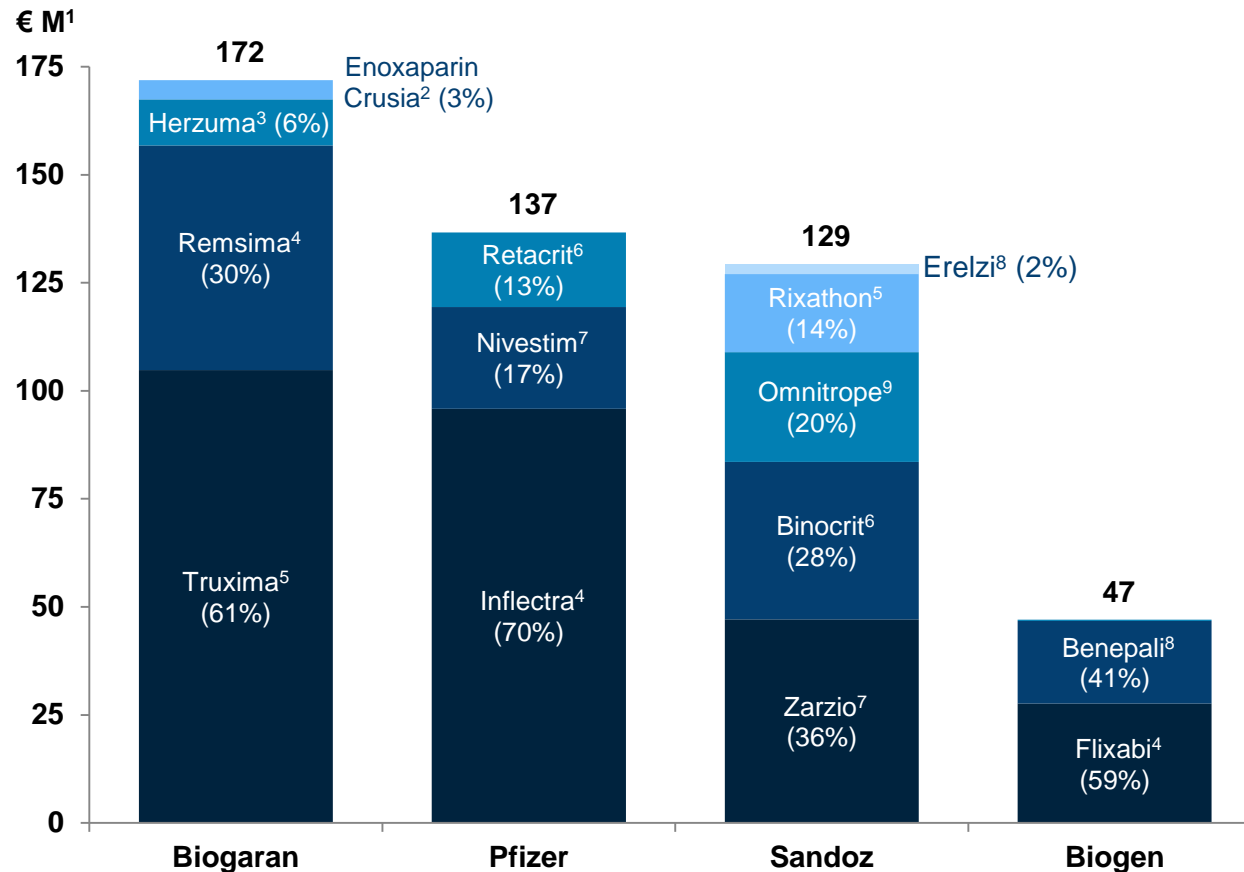


Sources: GERS – Smart Pharma Consulting analyses

¹ Both retail and hospital sales – ² Ex-factory price, excluding taxes and rebates –
³ Part of Aurobindo, since its acquisition of Actavis in 2014

In 2018, the top 4 companies operating on the French biosimilars market had from 2 to 5 brands, and sales split on the hospital and retail market segments

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



■ **Biogaran:**

- ~97% of prescriptions and sales come from hospital-only drugs (i.e. Truxima, Remsima and Herzuma) which are prescribed and dispensed at hospital

■ **Pfizer:**

- All biosimilars are either prescribed or initiated by hospital physicians
- 26% of the corresponding sales are purchased at retail pharmacies

■ **Sandoz:**

- All biosimilars are either prescribed or initiated by hospital physicians
- ~72% of Sandoz sales are generated at retail pharmacies

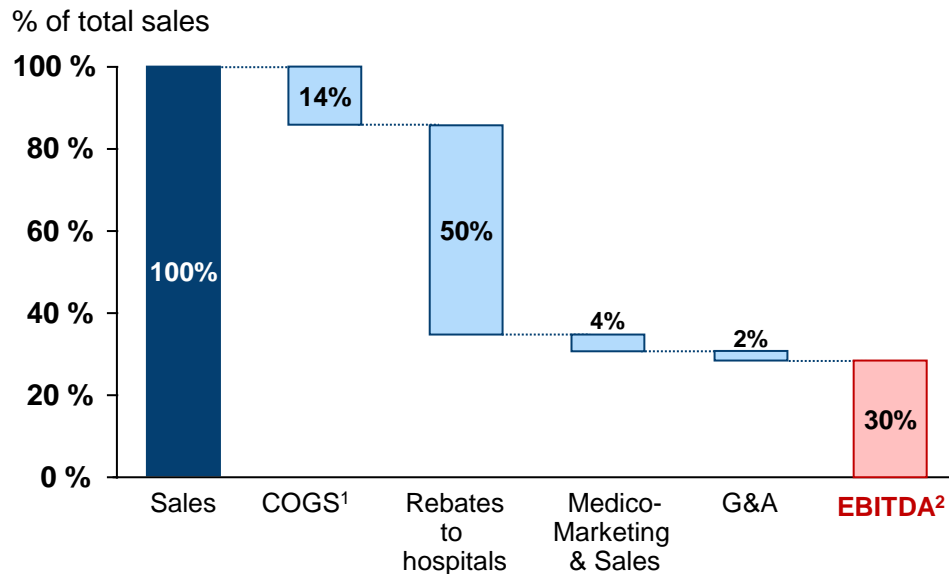
■ **Biogen:**

- All biosimilars are either prescribed or initiated by hospital physicians
- ~40% of sales are bought at retail pharmacies

The hospital-only biosimilar model appears to be less profitable than the hybrid one due to a much higher level of rebates granted by pharma companies

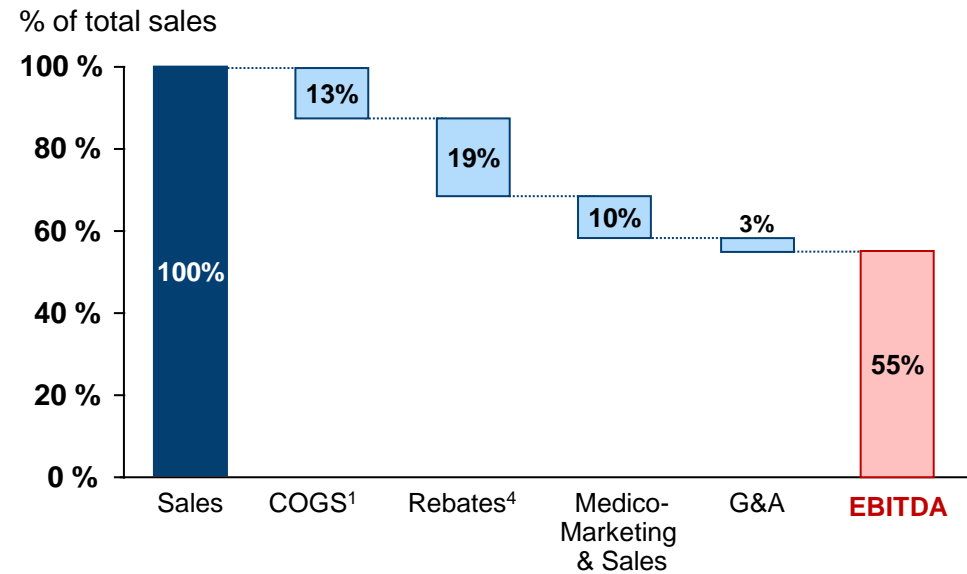
Estimated profitability of leading pharma companies on the biosimilars market (2018)

Hospital-only biosimilar model



- Estimates based on annual sales of € ~150 M generated by hospital-only biosimilars, with an average price list of 30% below the price of original brands before they enter the market
- Average discounts to hospitals: -50% on price list (ex-factory price)
- Medico-marketing and sales costs, incl.: 5 KAMs and 5 MSLS
- All other costs included in G&A³

Hybrid biosimilar model



- Estimates based on total annual sales of € ~130 M of which € ~90 M (72%) sold on the retail market, with an average price list of 40% below the price of original brands before they enter the market
- Average discounts to hospitals: -50% to -90% on price list⁴
- Medico-marketing and sales costs, incl.: 3 KAMs, 40 Reps and 4 MSLS
- All other costs included in G&A

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

¹ Cost of goods sold, including licensing fees and distribution costs – ² Earnings before interest, taxes, depreciation and amortization – ³ Registration costs, head office costs, management costs, support functions – ⁴ ~50% to hospital-only drugs, ~90% to non hospital-only drugs. No significant rebates granted to retail pharmacies

The most important success factor on the biosimilars market is to be the 1st market entrant and have the opportunity to remain the only biosimilar, for several months

Key success factors on the biosimilars market

#1 – Be the 1st entrant

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

#2 – Offer the best price

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

Key Success Factors

#4 – Develop services

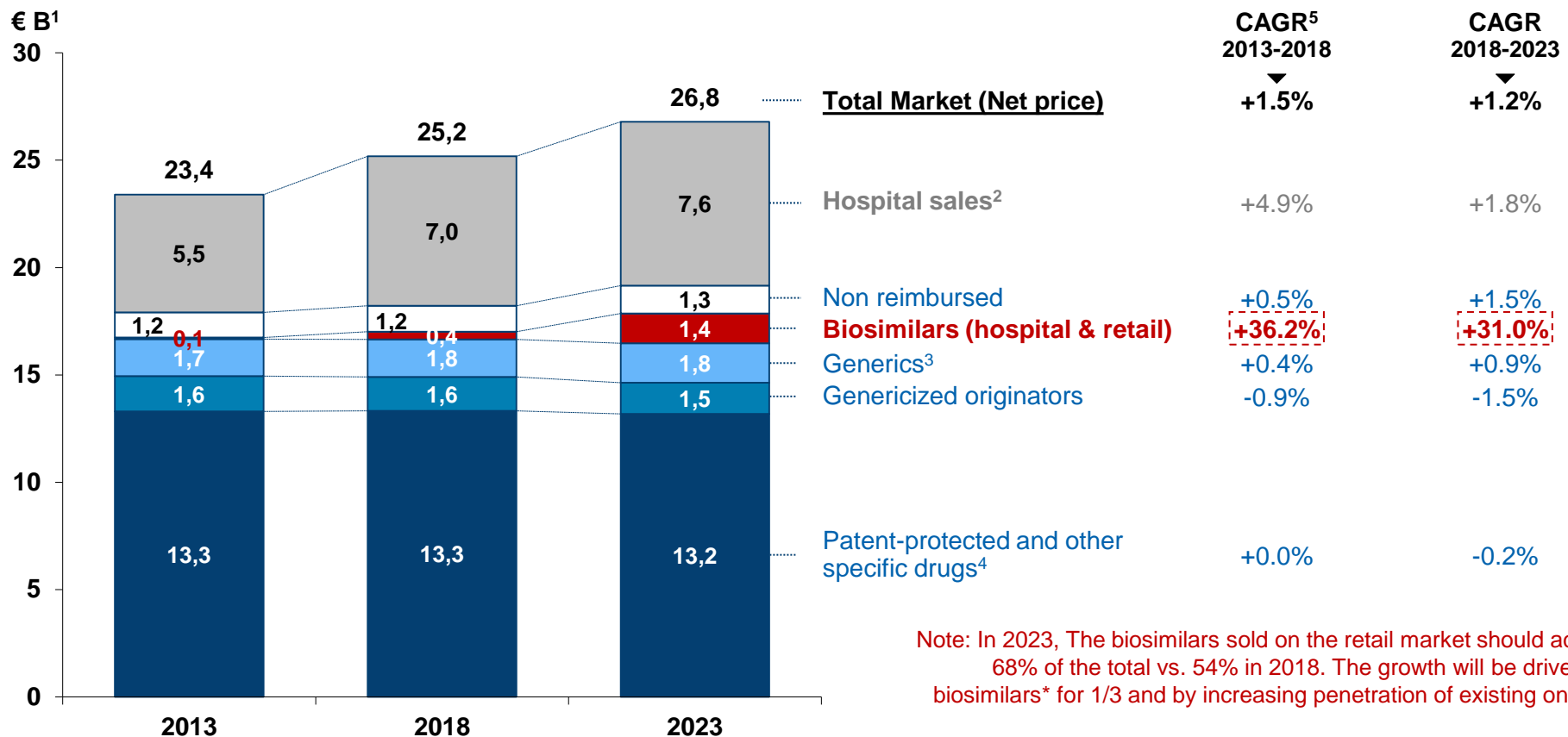
- Services proposed to hospital pharmacists, physicians, nurses and patients to facilitate the procurement, the prescription, the patient education and the drug usage may play a significant role to get preferred by hospital HCPs⁴
- The market insight (knowledge and understanding) of in-field collaborators is a prerequisite to deliver highly valued services
- The quality of services will reinforce the reputation of the biosimilars company and preference of HCPs for its products

#3 – Propose a better product

- There are possibilities to differentiate biosimilars amongst themselves and vs. the corresponding original biologic:
 - Amgevita (Amgen) and Hulio (Mylan) propose a citrate-free version of adalimumab, as Humira (AbbVie)¹ does since 2018, associated with less injection site-related pain²
 - Benepali (Biogen), a biosimilar of etanercept, has shown in a European study³ that its autoinjector was easier to operate and more intuitive to use compared with the Enbrel (Pfizer) one, according to 86% of the 149 nurses who had been interviewed

The biosimilars market should reach € 1.4 B in net value in 2023, with 1/3 of the growth driven by new biosimilars and 2/3 by increasing penetration of existing ones

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



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

Sources: GERS dashboards – Smart Pharma Consulting estimates

¹ Constant ex-factory prices including estimated rebates to hospital and retail pharmacists – ² Excluding hospital sales of biosimilars but including all other products on the hospital budget and products invoiced in addition of the hospitalization charges (on top of T2A) and reassigned medicine sales – ³ Reimbursable generics and quasi-generics – ⁴ Sales of drugs whose patents have not expired and of other specific products (calcium, sodium, potassium, paracetamol, etc.) – ⁵ Compound annual growth rate

The future growth of biosimilars will be mainly driven by health authorities measures introduced to boost HCPs¹ prescriptions and by LOE² of several high sales biologics

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

	Drivers	Limiters
Health authorities & Payers	<ul style="list-style-type: none"> Biosimilars can increase access to treatments by: <ul style="list-style-type: none"> Decreasing the overall treatment costs and thus Increasing affordability (treatment of larger populations) Increasing body of evidence showing the reliability, efficacy and quality of biosimilars 	<ul style="list-style-type: none"> “Precaution principle”: high cautiousness due to major public health issues in the past (e.g. blood transfusions contaminated with HIV, growth hormone case, sudden increase of pure red cell aplasia (PRCA) with Eprex³) Substitution permitted by law since Dec. 2013 but not implemented, in the absence of the corresponding decree
Hospital HCPs	<ul style="list-style-type: none"> They contribute to improve hospitals financial balance Objective of penetration set at hospital level (CAQES) Financial incentives proposed by health authorities for prescribing biosimilars (i.e. insulin glargine, etanercept, adalimumab) through the “article 51” experiment For physicians, biosimilars are an alternative to reference products (in case of shortage for instance) 	<ul style="list-style-type: none"> No guarantee of perfect equivalence with the reference product Physicians generally have close relationships for many years with original brand companies, which may discourage them to use (extensively) biosimilars
Patients	<ul style="list-style-type: none"> None, except in cases where patients might have to bear (totally or partially) the cost of biological drugs 	<ul style="list-style-type: none"> Preference for originators, on principle, especially in the case of serious and/or chronic diseases
Biosimilar companies	<ul style="list-style-type: none"> Increasing number of biosimilar products per molecule accelerates market penetration and reduces hospital prices ~13 biologics with high sales levels will lose their market exclusivity and face biosimilar competition by the end of 2023 	<ul style="list-style-type: none"> The intensification of competition drives biosimilar prices down and jeopardizes biosimilar companies profitability... ... rendering the market much less attractive for new players

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

¹ Healthcare professionals – ² Loss of exclusivity – ³ Increase in PRCA explained by an increase in the immunogenicity of Eprex following a formulation change in 1998, in which the human serum albumin stabilizer was replaced with polysorbate 80 and glycine

The market of biosimilars will benefit from the launch of new products in existing classes and in new classes by 2023

Executive summary

1. The market structure and dynamics

- Since 2014, the market has increased four-fold¹
- The penetration of hospital-only biosimilars is must higher than the one of biosimilars which are also delivered on the retail market

6. The 2018 – 2023 market growth

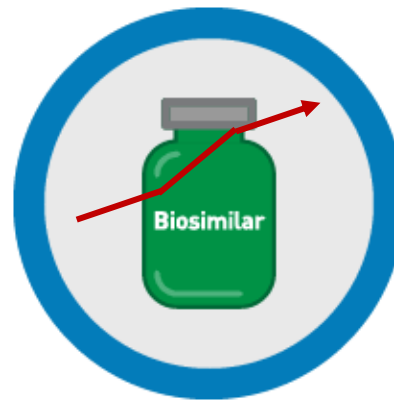
- The market should increase by € 1 B, thanks to the LOE of blockbusters (e.g. Avastin, Lucentis) and the increasing market penetration of recent biosimilars (e.g. Humira, Herceptin)

5. The key success factors

- Enter first the market
- Be the lowest-priced bidder...
- ... and/or offer superior services
- Offer a better product than competitors

2. The French regulatory environment

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



3. The customers behaviors

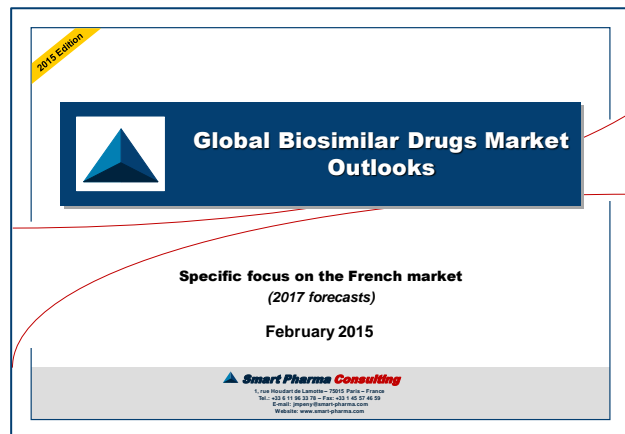
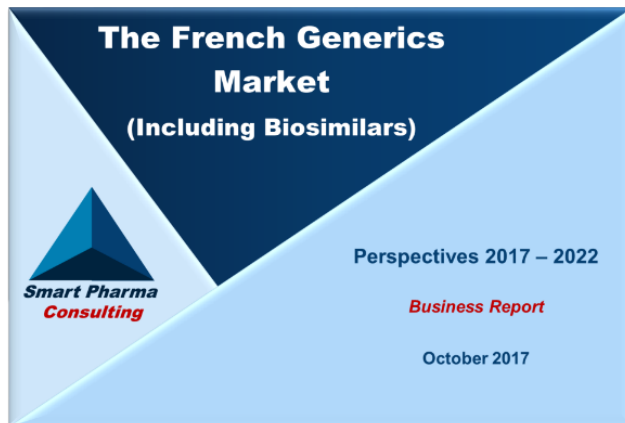
- Hospital listing and prescribing depend mainly on product attributes and price
- The absence of authorization for retail pharmacists to substitute biosimilars² makes physicians the main driver

4. The competitive landscape

- The top 3 leading players³ have generated more than € 100 M gross sales in 2018, accounting for ~82% of the market in value
- They have generated EBITDA⁴ rates ranging from 30% to 60% of gross sales

Smart Pharma Consulting has published several analytical reports and carried out consulting projects on biosimilars market attractiveness and key success factors

Selected publications & consulting projects on biosimilars



Examples of recent consulting projects

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

Hospital & Institutional Relationships in Regions

Benchmarking
study carried out
in France

Best-in-Class Series #9

Recommendations for
Pharma Companies

January 2019



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Consulting

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The evolution of the healthcare environment in regions should spur pharma companies to adjust hospital KAMs¹ and regional KIMs² roles and responsibilities

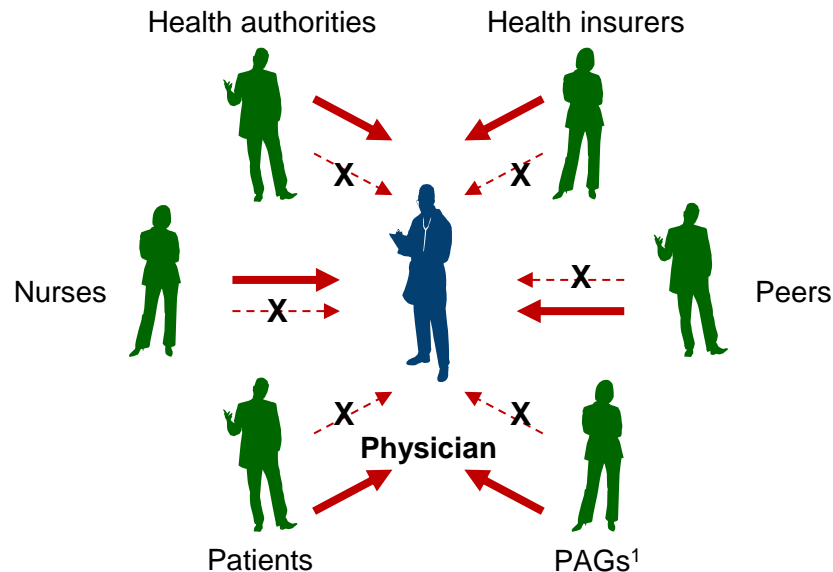
Scope & Objective of the study

- The purpose of this position paper is to **analyze** the **hospital KAMs** (Key Account Managers) and the **regional KIMs** (Key Institution Managers) **roles** and **responsibilities** and to discuss **the way** they **must adapt** to the **evolution** of the **regional healthcare environment** in France
- For so doing, Smart Pharma Consulting has:
 - **Reviewed** its previous **publications** on this topic
 - **Interviewed** senior executives from French affiliates of **7 pharma companies** (Biogen, Janssen, MSD, Pfizer, Roche, Novartis and Novo Nordisk) in July and November 2018
- Based on these information, Smart Pharma Consulting **proposes**:
 - **Strategic** and
 - **Organizational recommendations**regarding hospital KAMs and regional KIMs

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

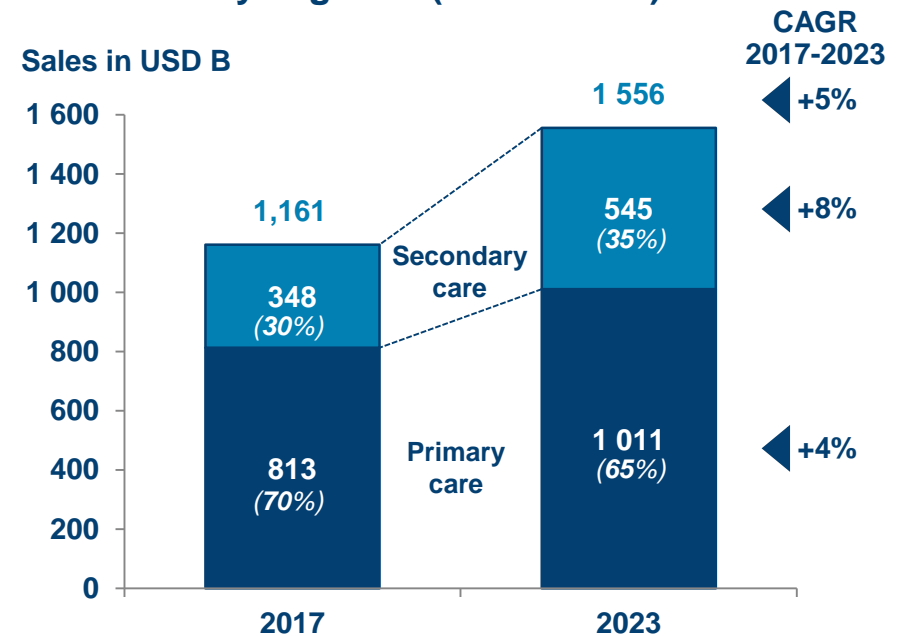
Evolution of the pharma market (1/2)

Therapeutic decision-making process evolution



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

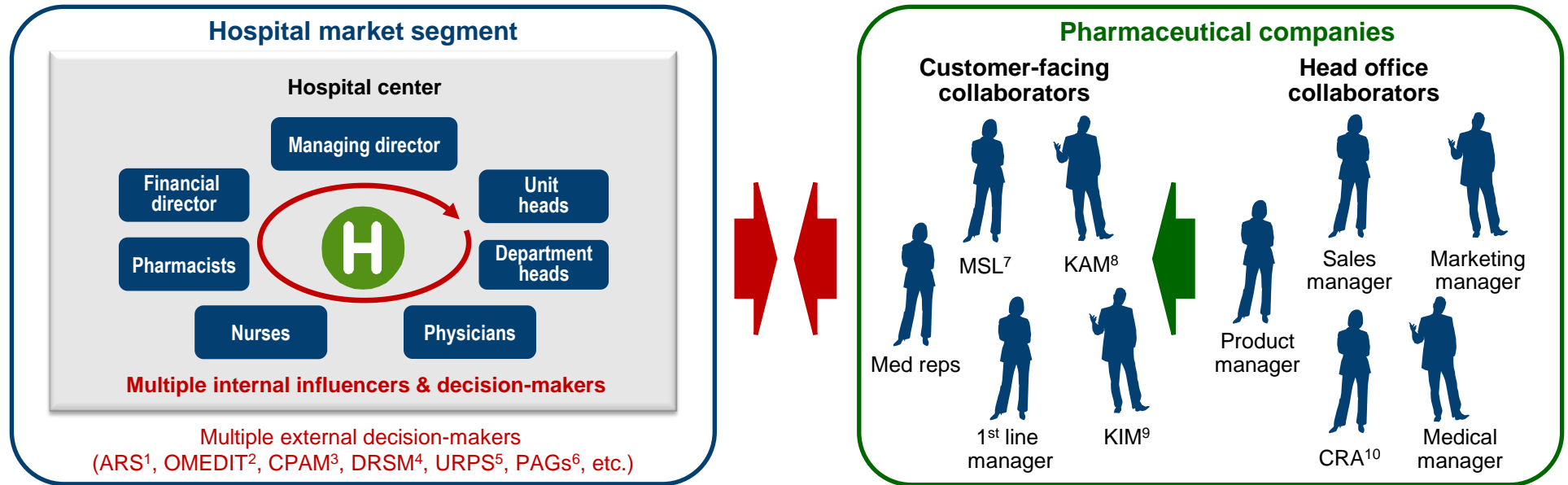
Global pharmaceutical market growth by segment (2017 – 2023)



Secondary care products which are mainly prescribed² in hospital centers should grow faster than primary care products mainly initiated and prescribed by office-based physicians

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

Evolution of the pharma market (2/2)

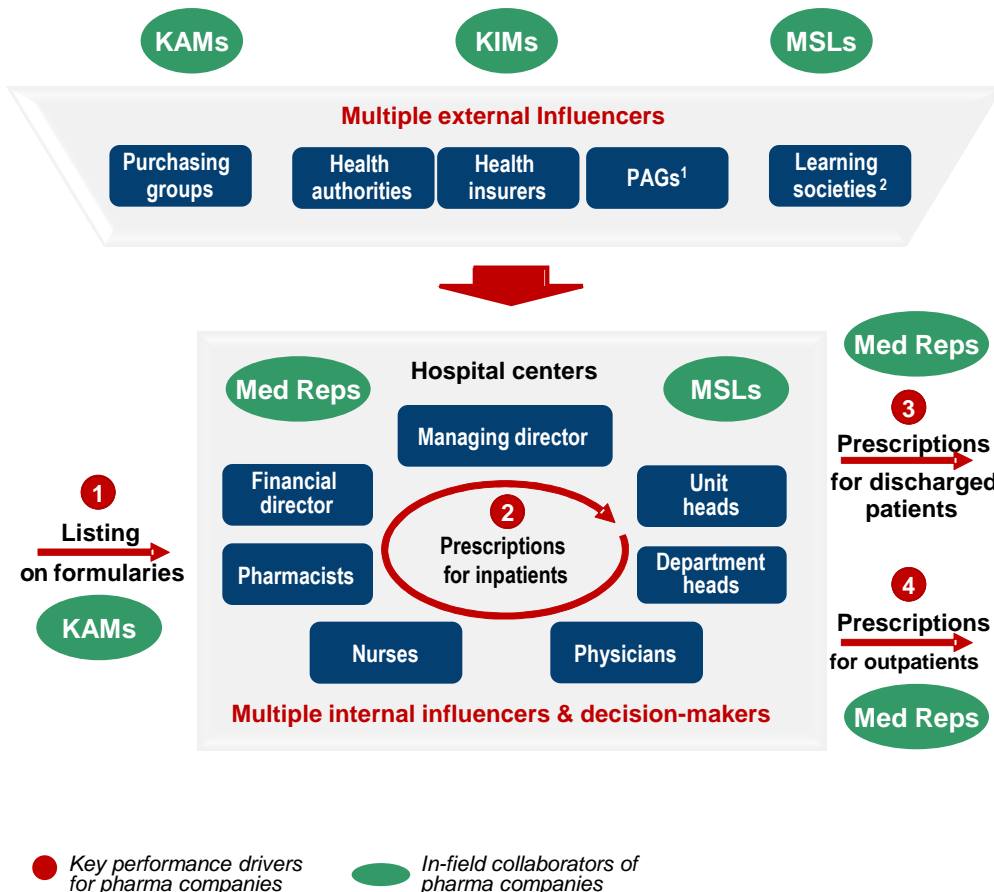


- The grouping of hospital centers has led pharma companies to deal with bigger accounts benefiting from a stronger bargaining power...
- ... in a context of economic pressure, making customers more price-sensitive than ever

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

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

Strategic levers at hospital key account (1/2)



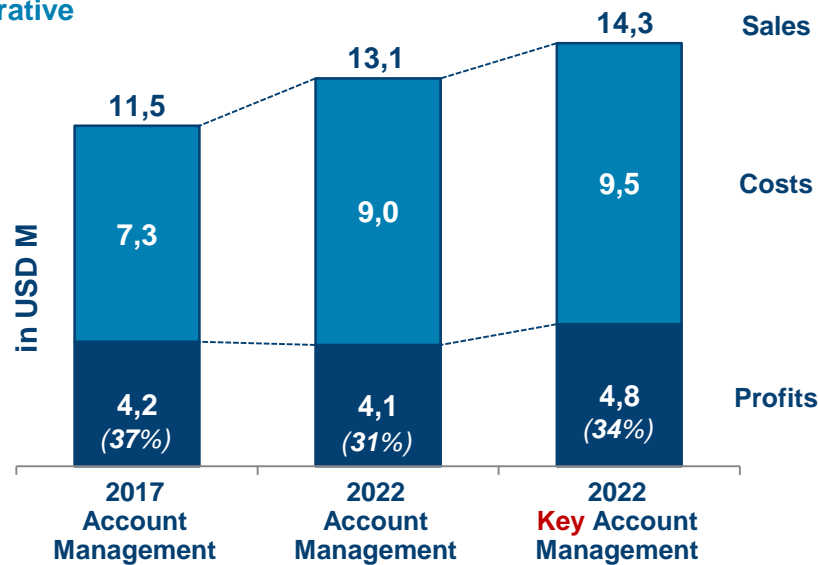
- To boost their hospital performance, pharma companies can activate several internal drivers:
 - The listing on formularies under the KAM responsibility (1)
 - The prescription for inpatients (2), discharged patients (3) and outpatients (4) under the Med Reps responsibility and the activities of MSLs
- Pharma companies may also act at the level of hospital external influencers such as:
 - National or regional purchasing groups through KAMs, along with collaborators such as: head of KAMs, commercial director
 - Health authorities, health insurers and regional branches of PAGs through KIMs
 - Regional branches of learning societies through MSLs

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

Strategic levers at hospital key account (2/2)

Expected impact from pharma company perspective

Illustrative



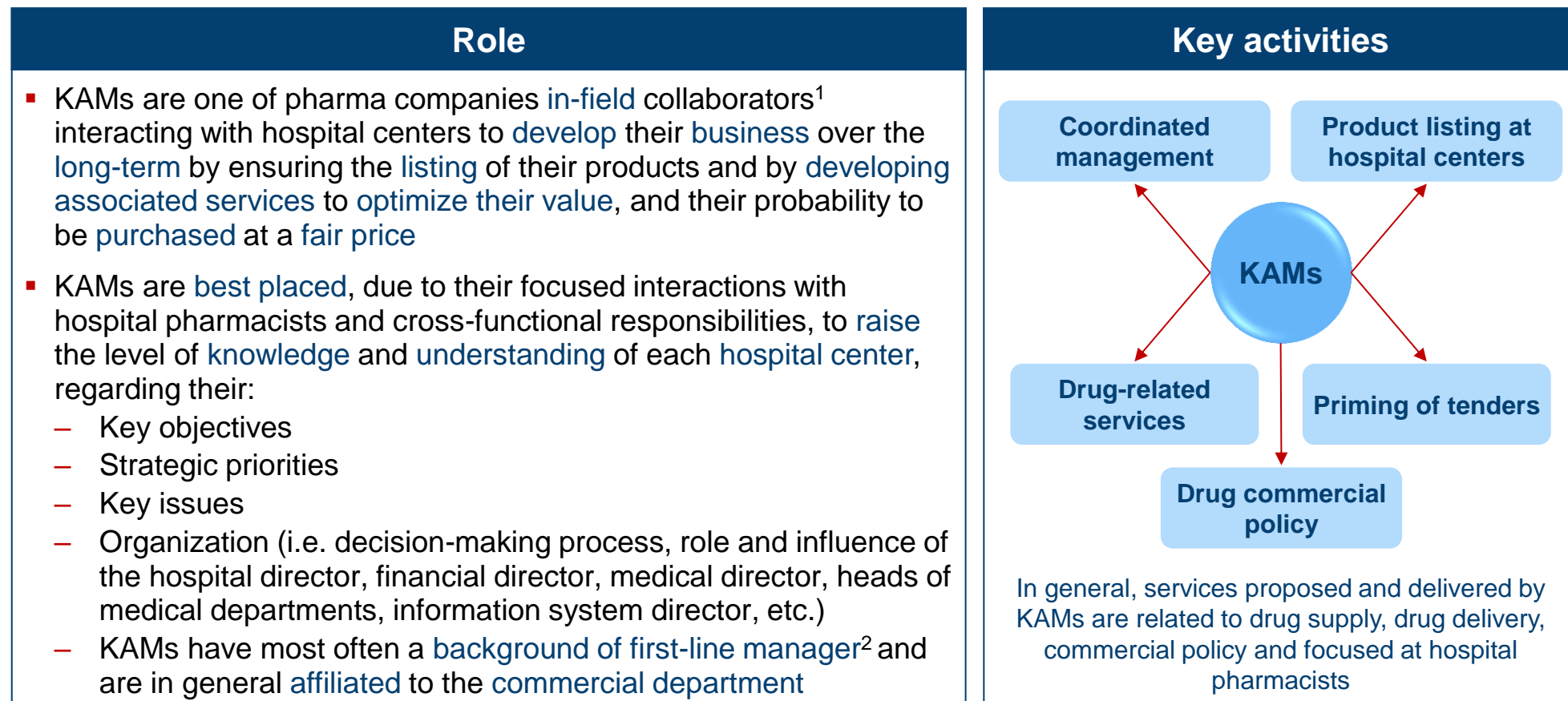
The specific management of hospital key accounts by pharma companies will generate extra costs due to the proposed services but should generate more sales, more profits and possibly higher profitability than a standard account management

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 KEIs¹ and KPIs² to deliver the expected joint value
- **#4:** The services should be clearly communicated by the collaborators of the pharma company and related to its product portfolio
- **#5:** Each hospital key account should be managed in a coordinated manner by cross-functional multidisciplinary internal and external stakeholders

KAMs are essential to get pharma companies products listed and bought by hospital centers and to ensure the proper coordination of activities carried-out by in-field teams

Role and core activities: Introduction

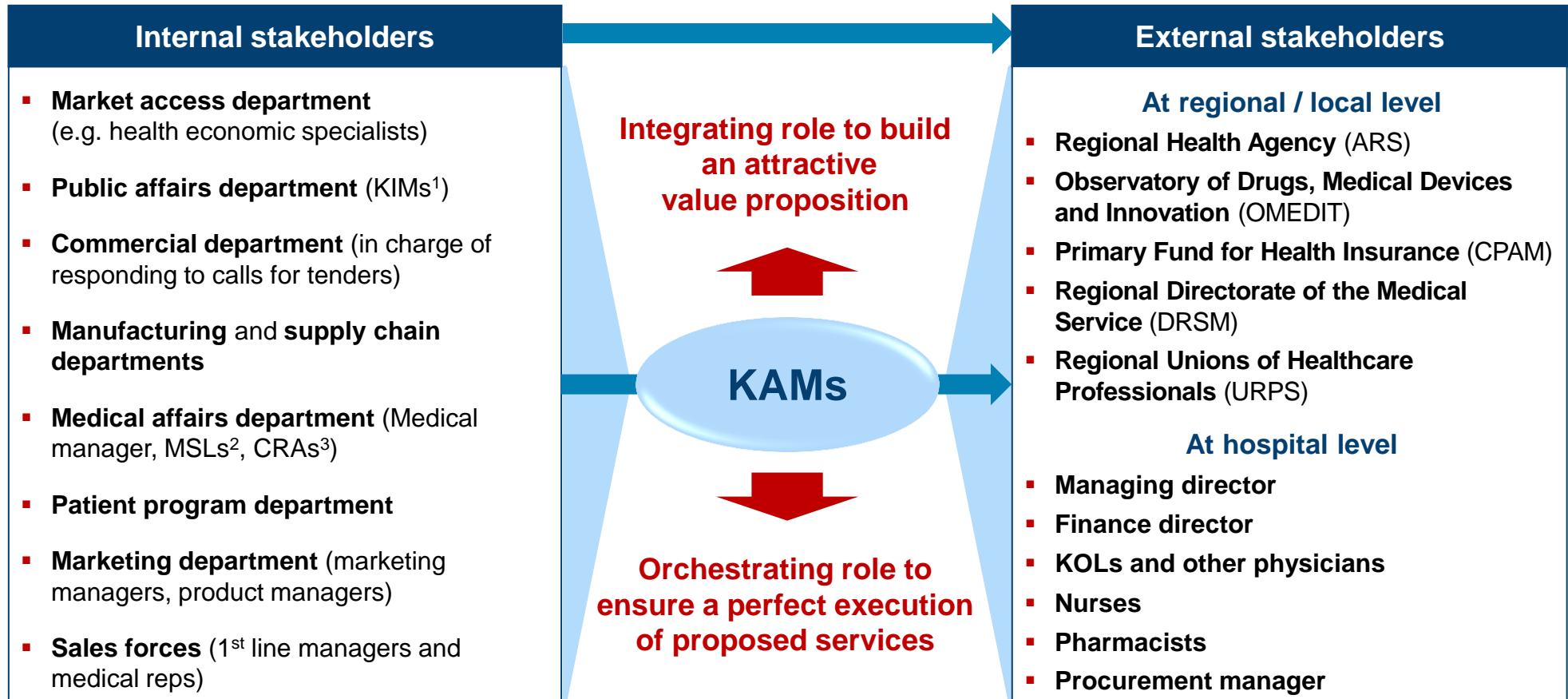


Sources: Smart Pharma Consulting

¹ Amongst other field teams we can mention: Medical Reps, MSLs (Medical Science Liaisons), KIMs (Key Institution Managers) – ² It is important to note that competent Medical Reps or 1st line Managers do not make necessarily competent KAMs. The skill set required for key account management role is much broader

The complexity of hospital KAMs role lies in the fact that they must deal with multiple internal and external stakeholders having different needs and priorities

Cross-functional role



The 5 key activities carried out by hospital KAMs are very similar from one company to another one

Key activities

Survey Outcomes

Key activities	Description
Listing	<ul style="list-style-type: none"> Coordination with Med Reps and MSLs to convince prescribers, members of the hospital listing committee, to get the company products listed and to help them fill up the dossier to motivate the listing of the concerned products¹ Coordination with other KAMs to deliver the same information when decision-makers, for a given call for tenders, belong to purchasing groups at national (e.g. UNI-HA), regional and local (e.g. Hospital Territory Groups) levels It is essential to anticipate and work upstream with these different decision makers, in a coordinated manner
Tender priming	<ul style="list-style-type: none"> Tender priming requires a coordinated approach led by the KAMs and based on tangible differentiating points to motivate a more favorable design of lots called for tenders
Commercial policy	<ul style="list-style-type: none"> The commercial policy is set with or without prior agreement² Analysis of earlier calls for tenders provides information to potentially adjust prices for the others to come KAMs are also involved in negotiated contracts to set the commercial terms
Drug-related services	<ul style="list-style-type: none"> KAMs can propose drug-related services which can count up to ~20% of the final mark in the evaluation of the bids for calls for tenders, as Corporate Social Responsibility initiatives can do (up to 10%) Certain companies bring their support and propose solutions to hospital centers to improve their efficiency (e.g. revision of terms of payment, conditions of supply, day care organization)
Coordinated management	<ul style="list-style-type: none"> To support the coordination of hospital centers and especially of key accounts, some pharma companies have developed a “key account plan” but, for compliance reasons, the KAMs, KIMs, MSLs and Med Reps sections are not shared on the same document or partially shared (e.g. Intranet with shared and non-shared sections) The KAM is key to raise the knowledge and understanding of hospital centers, especially if he maintains good relationships with hospitals pharmacists who, in general, have a privileged position

The number of KAMs per company is mainly driven by the size of the hospital-only product portfolio and to the organizational model which has been chosen

Organization and targeted clients

Survey Outcomes

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

Sources: Smart Pharma Consulting

¹ Organizational model: some companies have opted for a hybrid model in which the same collaborator ensures the role of KAM and KIM (Key Institution Manager) at the same time – ² Full Time Equivalent

KAMs and departments in charge of responding to calls for tenders must collaborate closely to optimize their chances to win calls for tenders

Interactions with the response to calls for tender department — Survey Outcomes

Response to calls for tender department

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

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

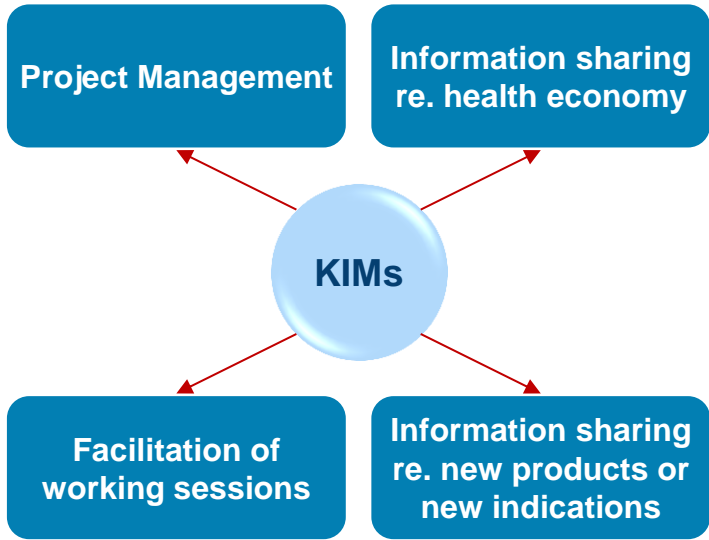


KAMs

- The KAMs will review the list of lots that are called for tenders
- They will collect qualitative and quantitative information, mainly through hospital pharmacists in charge of drugs procurement, to adjust the therapeutic and technical specificities of their products and the associated services they want to highlight
- They are responsible for setting the commercial policy, with a degree of autonomy which is very different from one company to another¹
- Based on the analysis of the information collected by the response to calls for tender department and by them, they may revise their price for the new calls for tenders to come

Regional Key Institution Managers role is focused at ARS¹, OMEDIT², CPAM³, DRSM⁴, URPS⁵ who can have an influence on hospital centers decisions related to drugs

Role and key activities

Role	Key activities
<ul style="list-style-type: none"> ▪ The KIMs role is to interact with regional/local health institutions (e.g. ARS, OMEDIT, CPAM, DRSM, URPS) and for certain companies with local politicians (e.g. Members of Parliament, Senators, Mayors) to optimize the conditions of use of the key products marketed by the pharma company they work for ▪ Thus, KIMs do not promote products ▪ KIMs may also be responsible for improving the reputation of their company by carrying out various initiatives that are likely to have a positive impact on public health at a regional/local level ▪ KIMs may have different backgrounds (e.g. marketing, sales, market access) and are affiliated, in general, either to the commercial department or the market access department ▪ They need to have a solid knowledge and understanding of the healthcare system at national, regional and local levels ▪ They must be able to manage projects 	 <pre> graph TD KIMs((KIMs)) --> PM[Project Management] KIMs --> ISHE[Information sharing re. health economy] KIMs --> FWS[Facilitation of working sessions] KIMs --> ISNPI[Information sharing re. new products or new indications] </pre> <p>To carry out these activities, KIMs interact with health institutions by calling on them, inviting them to symposiums and proposing them or co-building with them healthcare projects</p>

KIMs activities consist in sharing information to raise the interest of institutions about their company portfolio, the disease they address and in managing healthcare projects

Model – staffing – key activities and target clients

Survey Outcomes

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

Sources: Smart Pharma Consulting

¹ Organizational model: some companies have opted for a hybrid model in which the same collaborator ensures the role of KIM and KAM at the same time – ² Full Time Equivalent – ³ Information System Director at hospital level

Regional institutions are little inclined to interact or collaborate with pharma companies, unless they propose and contribute to a public healthcare project of interest to them

Mutual expectations between KIMs and targeted clients

Survey Outcomes

Target clients	Importance L – M – H*	Accessibility L – M – H*	Expectations of targeted clients from pharma companies	Expectations of pharma companies from targeted clients
OMEDIT ¹	H	M	<ul style="list-style-type: none"> Information sharing regarding products marketed by the companies, especially for new products or new indications of products yet marketed 	<ul style="list-style-type: none"> Getting an opinion / advice before implementing a project to evaluate the benefit of a drug or a therapeutic strategy at the regional level Facilitation of early access for innovative drugs (e.g. screening of patients with biomarkers)
CPAM ²	M	L	<ul style="list-style-type: none"> No expectations CPAM distrust pharma companies and therefore do not want to interact with their collaborators 	<ul style="list-style-type: none"> To have the possibility to inform the CPAM re. new indications, prices, etc. for a product to avoid them to convey erroneous information to physicians that could negatively impact its performance
DRSM ³	M	L	<ul style="list-style-type: none"> No expectations because they distrust pharma companies 	<ul style="list-style-type: none"> To have the possibility to meet them to address specific problems about products indications, use, etc.
URPS ⁴	M	M	<ul style="list-style-type: none"> Provide an organizational and a financial support to carry out trainings, screening campaigns at regional level 	<ul style="list-style-type: none"> URPS are a useful relay to inform and mobilize their members to participate to healthcare projects (e.g. screening campaigns, initiatives to improve adherence of patients to treatments)
ARS ⁵	M	L	<ul style="list-style-type: none"> Limited or no contact, because they do not want to collaborate with pharma companies or because the latter are not a priority for them 	<ul style="list-style-type: none"> To set up healthcare projects and get their approval Convince ARS to allocate specific resources (financial and/or human) for a better management of the diseases for which the company products are indicated

* L: low – M: medium – H: high

Depending on the project, regional KIMs can propose a scientific, logistics or financial support to public healthcare projects or projects to improve the proper use of drugs

Examples of projects carried out with regional institutions

Survey Outcomes

Project #1: The Immunization Day

Project #2: Drug Fact Sheet

Objectives

- Scientific support
- Logistics support
- Formatting of messages

- Writing of a drug fact sheet for a new product...
- ... while transitioning from the ATU (Temporary Use Authorization) status to the post-ATU one
- Set up of working groups in regions

Partners

- ARS
- CPAM

- OMEDIT

Duration

- 1 month

- 2 months

Conclusion

- Impact on medical practices: raise the awareness re. the pharmaceutical conciliation¹ especially during the patient transition from hospital to ambulatory care
- Publication of the results

- This drug fact sheet has shown to be useful especially to inform the pharmacists...
- ... and thus to guarantee the proper and safe use of this new drug

These two projects show the ability of pharma companies to bring together diverse expertise to produce recommendations or carry out pilot projects related to healthcare

Examples of projects carried out with regional institutions

Survey Outcomes

Project #3: Innovation in Oncology

Project #4: AMD¹ Screening in Region

Objectives

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

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

Partners

- 113 experts

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

Duration

- 2 years

- 4 weeks

Conclusion

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

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

Projects managed by regional KIMs may (should) contribute to raise the value of the response to the calls for tenders, as illustrated in this example

Examples of projects carried out with regional institutions

Survey Outcomes

Project #5: Hospital Day Care Management

Objectives

- Measurement of time spent by patient
- Search of solutions to reduce the cost of hospital day care against diagnosed-related groups (DRG)
- Methodological contribution to the hospital center

Institutions

- Hospital centers

Duration

- 3 to 6 months (delay due to the time required to get the agreement from the hospital director)

Conclusion

- This has enabled hospital centers to improve their efficiency while managing drug perfusion to patients
- This service has been highlighted in the responses to calls for tenders

The services proposed must offer tangible benefits to the targeted customer and to the pharma company by improving access and usage of its products

Examples of services for hospital centers and regional institutions

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

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

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

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

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

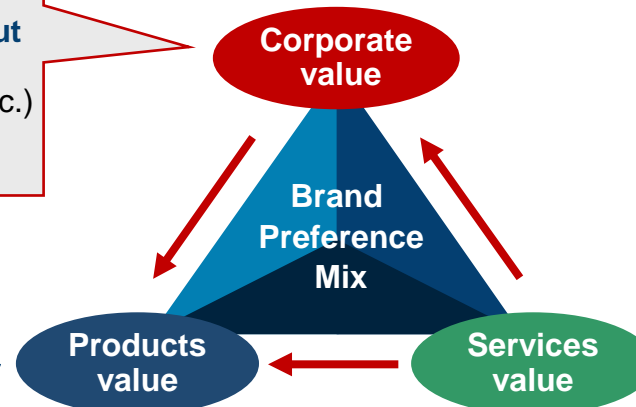
From the pharma company perspective, the value of the proposed services should be translated into higher product sales and associated profits

Impact of services on pharma company performance

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

- KAMs and KIMs should **communicate once or twice a year information about their company** (e.g. R&D news, CSR¹ initiatives, specific services delivered, etc.) to hospital stakeholders and regional institutions

- The direct or indirect² **impact of services** on products will be **objectivized** by the **positive evolution** of their **performance drivers** in **hospital centers**:
 1. Listing on formularies
 2. Prescription for inpatients
 3. Prescription for discharged patients
 4. Prescription for outpatients



- The **perceived value** of the proposed **services** by KAMs and/or KIMs at hospital center level will **depend on** their **ability** to:
 - Reduce hospital costs
 - Improve operational management
 - Improve medical management...
- ... and on their **quality of execution**:
 - Planning
 - Execution *per se*
 - Monitoring
- These services should have a **positive impact** on **corporate reputation** and **products perception** of the pharma company

The activities of in-field collaborators interacting with the same hospital center should be integrated in a single key account management plan, including separated sections

Integrated Key Account Management Plan

MSL Section

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



Marketing & Medical Rep Section

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

KAM Section

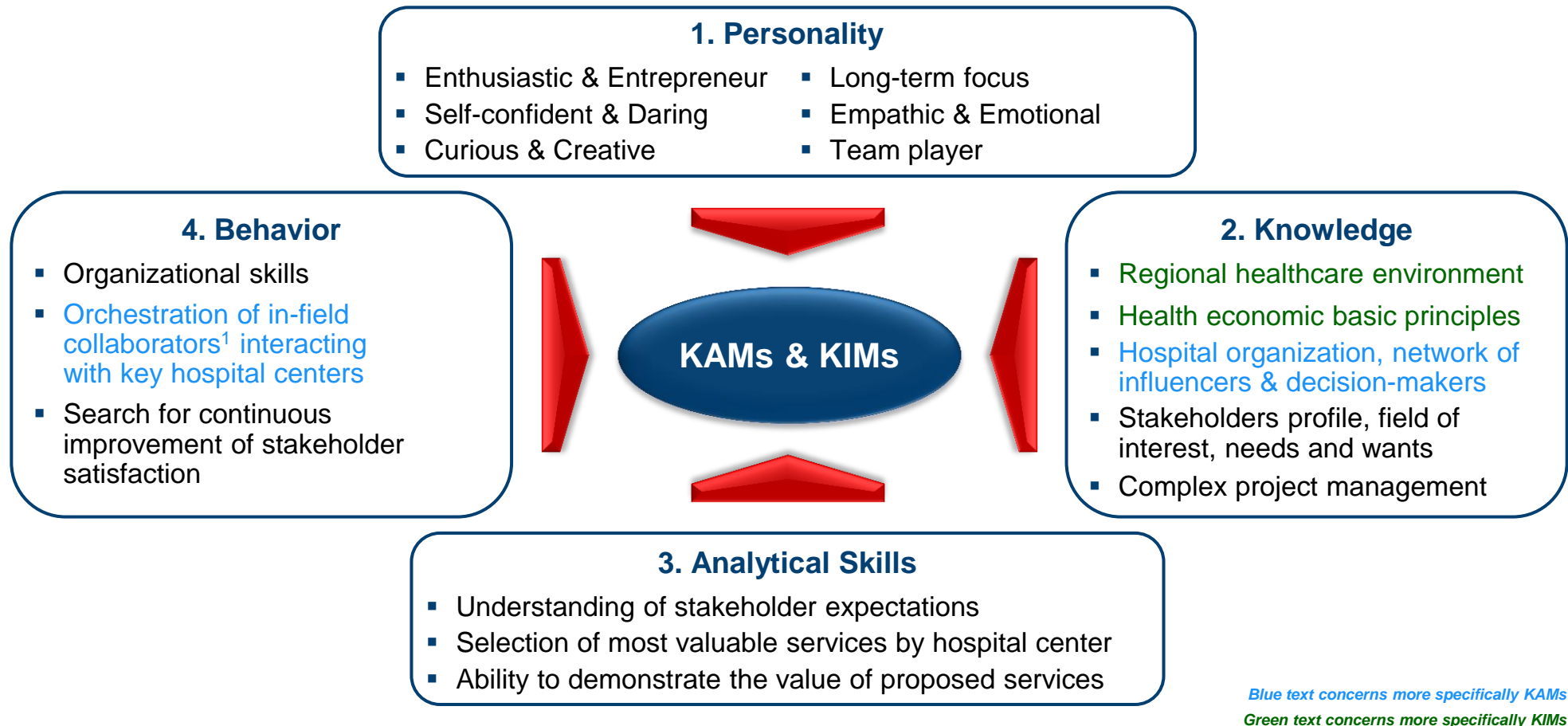
- **Key clients:** hospital pharmacists, purchase managers, director
- **Key objectives:** facilitate the hospital listing of drugs and maximize the chances to win the calls for tenders and get a fair price when products are bought through negotiated contracts
- **Key activities:** develop close relationships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

KIM Section

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

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

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



The performance and activities of KAMs and KIMs are evaluated with the help of KPIs and KEIs respectively, as indicated by interviewed senior executives

KPIs & KEIs¹

Survey Outcomes

Key Performance Indicators (KPIs)

- **Hospital Listing** (Yes / No)
- **Calls for tenders** (Won / Lost)
- **Average price level** (actual vs. budgeted)
- **Sales performance** (Units sold per month per hospital center)
- **Savings due to optimized management of products whose patent has expired**
- **Customer preference survey** (Brand Preference Mix¹)
- **Reputation assessment survey** (Pharma Reputation Index¹)

Key Execution Indicators (KEIs)

- **Number of contacts** (F/F. phone, e-mails)
- **Activity planning** (e.g. quality of tendering planning)
- **Quality of execution of the action plan** (e.g. % of applications sent on time for calls for tenders)
- **Project management** (compliance with project deadlines, satisfaction of targeted customers re. the project development and execution)
- **Coordination of the in-field team members activity per hospital center** (e.g. frequency and quality of interactions, relevance of joint-activities, respect of compliance rules)

Blue text concerns more specifically KAMs

Irrespective of their competence, KAMs and KIMs should dramatically improve their performance if they implement our recommendations in a rigorous and systematic way

Recommendations

Objective

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

Strategy

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

Organization

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

Strategic KOL Engagement Planning...

Concepts
Methods
&
Tools

... For a better
Efficacy & Efficiency



Smart Pharma
Consulting

Position Paper

May 2019

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

Context & Objective

- **KOLs¹ are part of the means used by pharma companies to:**
 - Develop their products through pre-clinical and clinical trials
 - Disseminate information (scientific, medical, therapeutic, etc.) to raise health authorities, payers, HCPs (Health Care Professionals), PAGs (Patient Advocacy Groups), individual patients awareness to optimize the positioning and the usage of their products

- **This position paper:**
 - Reviews the best practices in terms of KOL engagement
 - Proposes a simple but rigorous approach and...
 - ... a set of practical tools...

... to recruit, engage and manage KOLs

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

KOLs have the potential to influence their peers, but also other stakeholders in a specific area, at global, international, national and local levels

Working definitions (1/2)

KOL (Key Opinion Leader)

- KOLs are also called: Key Experts, Key Therapeutic Area Experts, Key Scientific Experts, Thought Leaders, Influencers, depending on the companies
- KOLs are **recognized** physicians with an **expertise in a specific field** (e.g. oncology, endocrinology, epidemiology, biostatistics, etc.)...
- ... and can **influence the opinion** and **the medical practice** (e.g. treatment scheme, prescribing habits, preference for a given product, etc.) **of their peers** (specialists or GPs)
- KOLs contribute also to **modify medical guidelines** when they are members of learned societies or when they advise health authorities
- Their influence can be global, international, national or local
- Other stakeholders are also considered as KOLs¹

Pyramid of influence & types of influencers



Strategic KOL Engagement Planning is essential for pharma companies to ensure an effective, efficient and sustainable relationship with KOLs

Working definitions (2/2)

KOL Engagement

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

Strategic KOL Engagement Planning

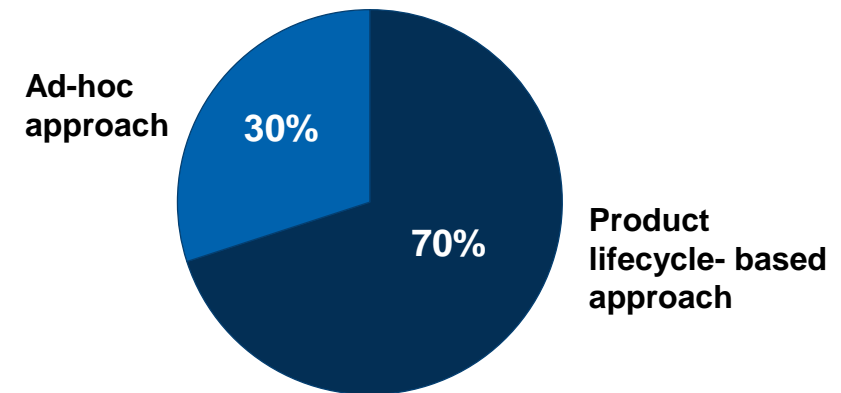
- Considering the **increasing complexity** of the pharmaceutical **environment** and of **pharma companies** organizations¹, it is essential to **plan** and **organize** the **interactions with KOLs**
- Thus, pharma companies should develop Strategic KOL Engagement **Plans** to **ensure**, as a general rule, that KOL Engagement **initiatives**:
 - **Support** the Critical Success Factors (**CSF**) to fulfill the corresponding Strategic Imperatives (**SI**) of the related product
 - Are put in a **mid- to long-term perspective** to **build** a **sustainable** win-win **relationship**
 - Are carried out in a **coordinated manner** across the company departments and from headquarter to affiliates to **guarantee** an **optimal efficiency**

More and more pharma companies are adopting an integrated strategic approach of their relationship with KOLs, based on their product position on their life cycle

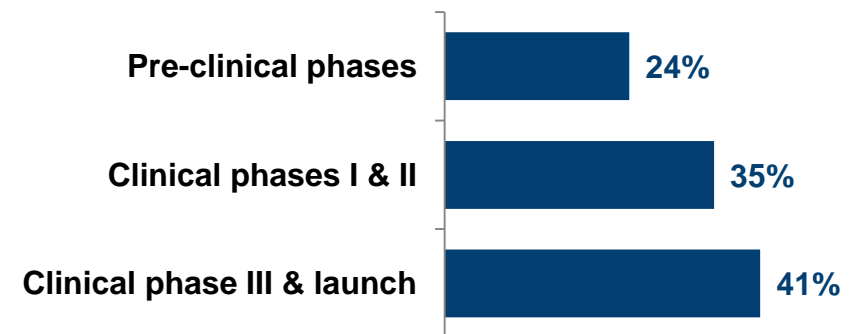
Types of KOL engagement

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

KOL engagement approach



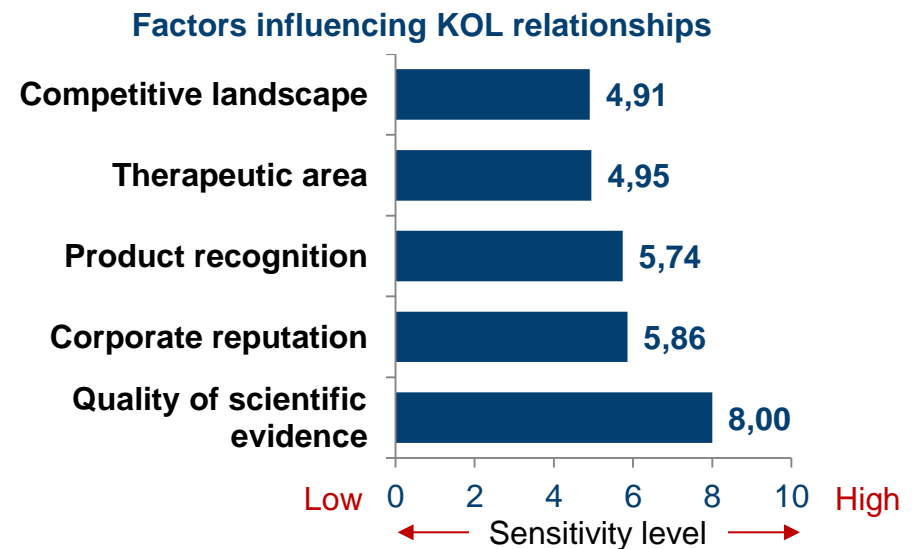
KOL engagement according to product lifecycle



The strength of KOL engagement will strongly depend on the quality of scientific evidence related to the product as well as on corporate and product perception

KOLs engagement & Influencing factors

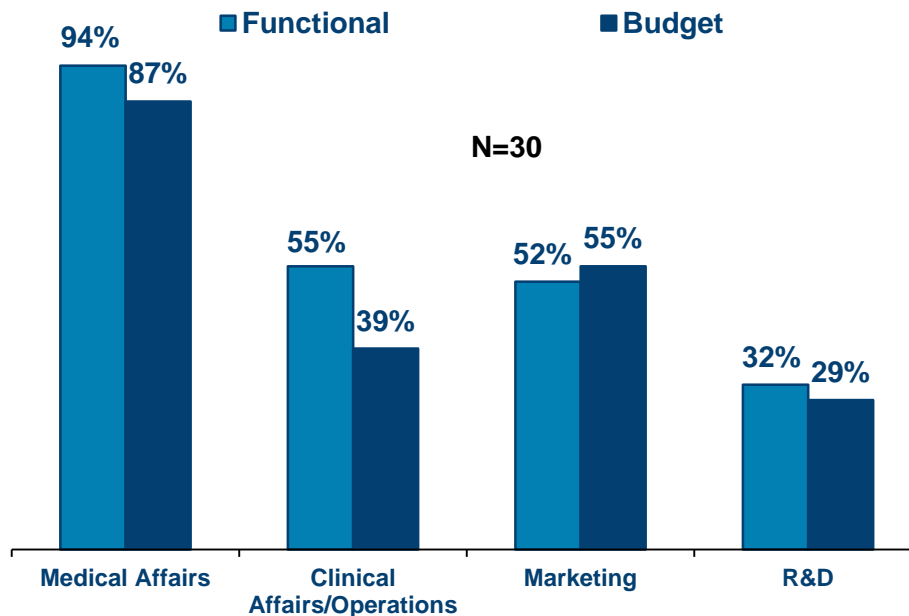
- From preclinical to phase II studies, Global KOLs are engaged to carry out scientific and clinical activities
- At phase III level, Global, International and National KOLs are mainly involved in clinical studies and in disseminating scientific information to physicians communities
- While preparing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



The hybrid and centralized management of KOLs are viewed as optimal by interviewees as they enable better coordinated and more consistent interactions

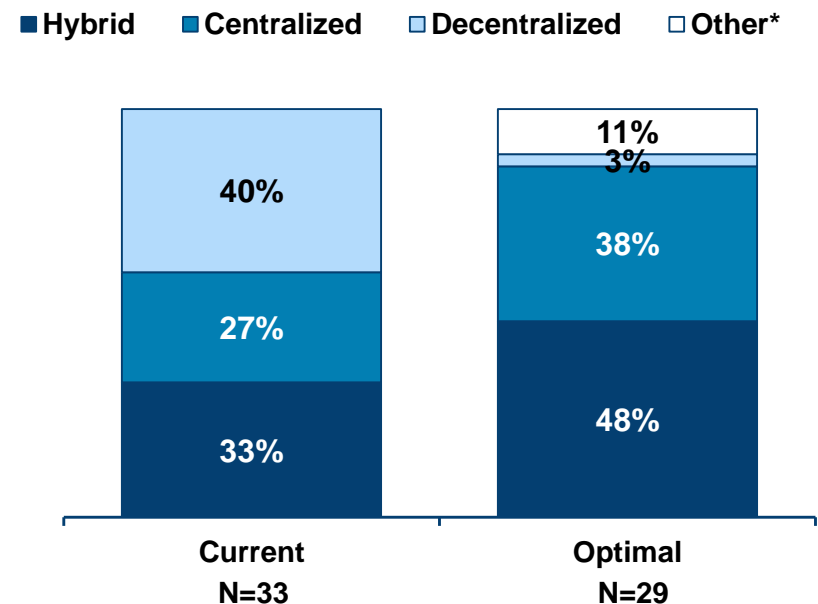
KOLs management by pharma companies

KOL Management responsibility at pharma companies



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

KOL Management organization at pharma companies



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

If KOLs services are mainly focused on clinical research, clinical advisory boards and disease state awareness exchanges; their impact is most often not formally evaluated

Main KOLs services & assessment

Most important services carried out by KOLs

N=28



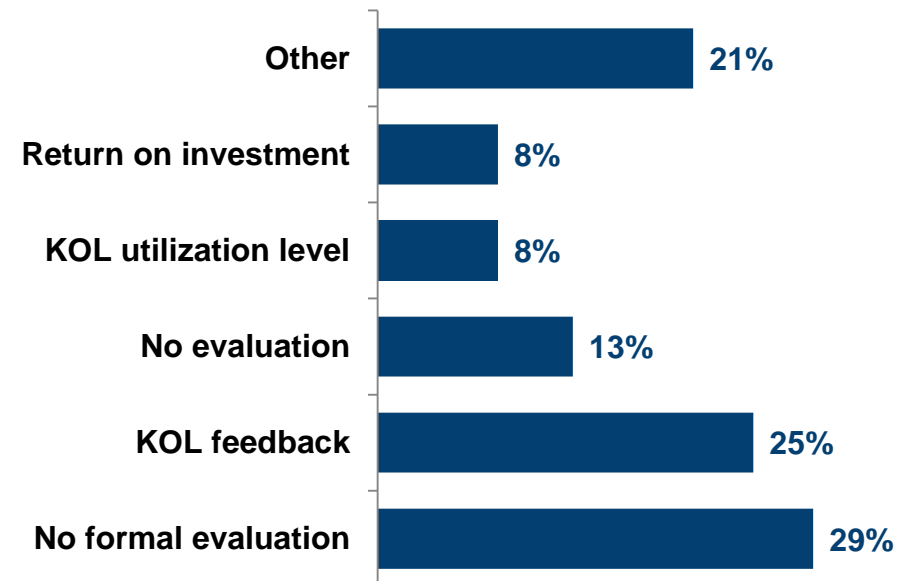
Mean score: 75

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

- Clinical research support, participation to medical advisory boards and disease state awareness are viewed as the most important KOLs activities

Evaluation of KOL Management & Engagement

N=24

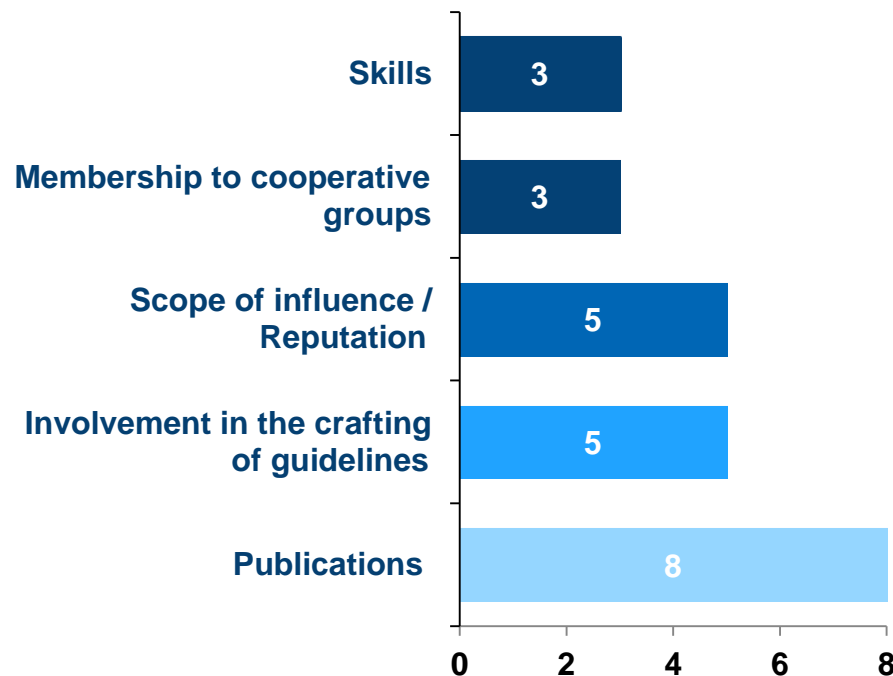


- There is no formal nor systematic measurement of the impact of KOLs engagement carried out by most of the pharma companies from the panel

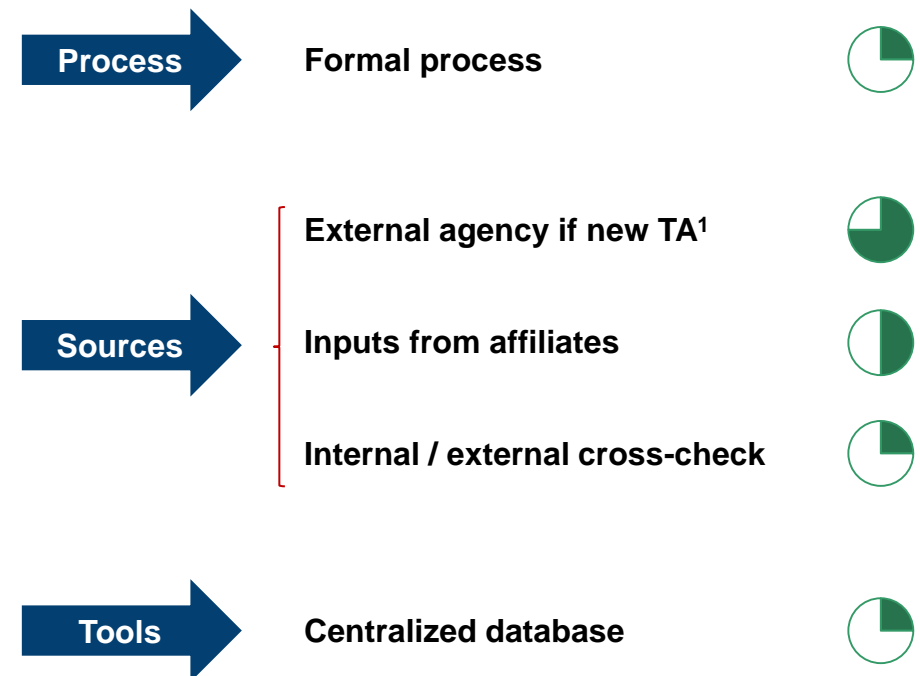
Few of the 8 benchmarked pharma companies have put in place a systematic and formalized process to qualify and select Global KOLs

Global KOLs qualification & selection

Main criteria to select Global KOLs



Data gathering



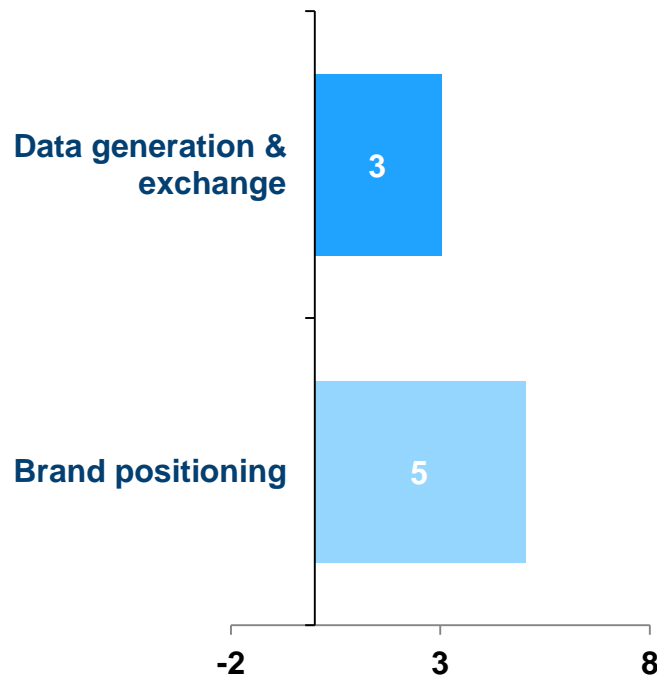
Note: Behavior & personality has been mentioned by one interviewee, as well as KOLs field of interest

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

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

Main objectives while engaging with Global KOLs

Main objectives¹



“While engaging with a KOL, we make sure he is interested by the project on which we want to involve him”

Objective setting

No formal approach, based on specific KOL expertise and company needs



Objective alignment on product Strategic Imperatives & Critical Success Factors

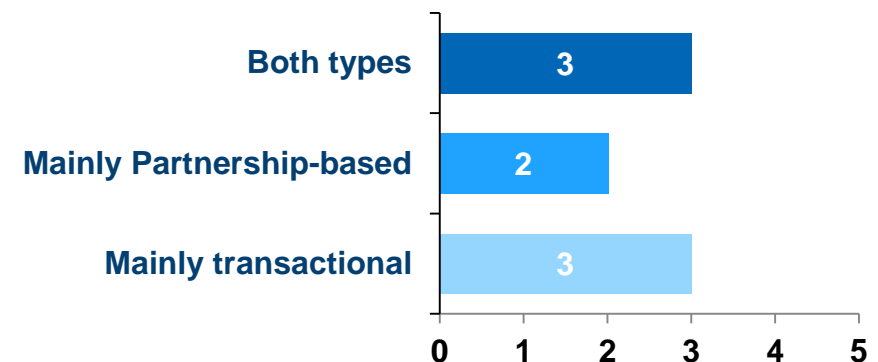
No formal alignment / no global vision



Alignment on Global Strategic Brand Plan / R&D Plan / Global Medical Affairs Plan



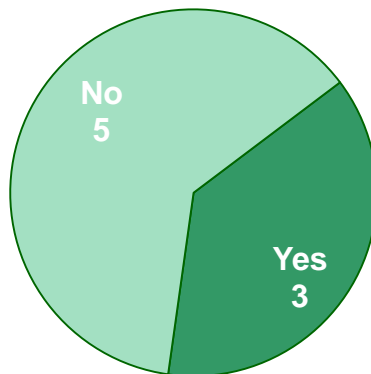
Type of agreements



Global KOL engagement plans are most often not formalized for each KOL and their follow-up over time is far from being systematic

Global KOL engagement planning & execution follow-up

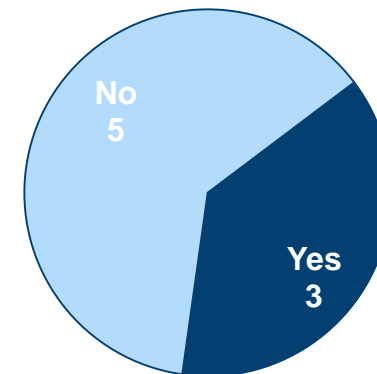
Global KOL engagement plans



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

Execution quality follow-up

System to monitor the implementation of Global KOL engagements



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

Main difficulties while engaging with Global KOLs

Poor internal alignment and multiple contact points

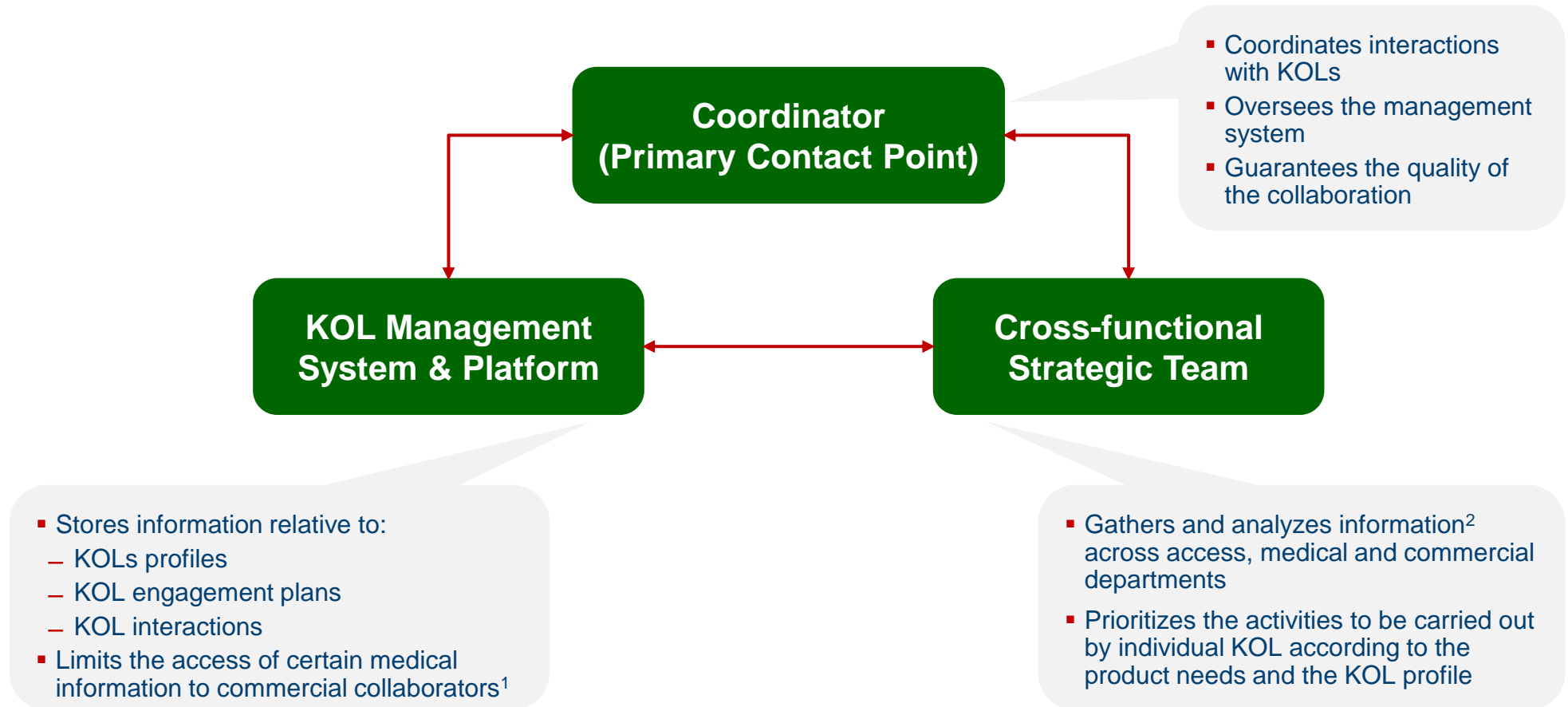


Overbooked and overused KOLs



The effective KOL management requires a cross-functional team working in the same direction, in a coordinated manner, with the help of a shared information system

Strategic KOL Management components

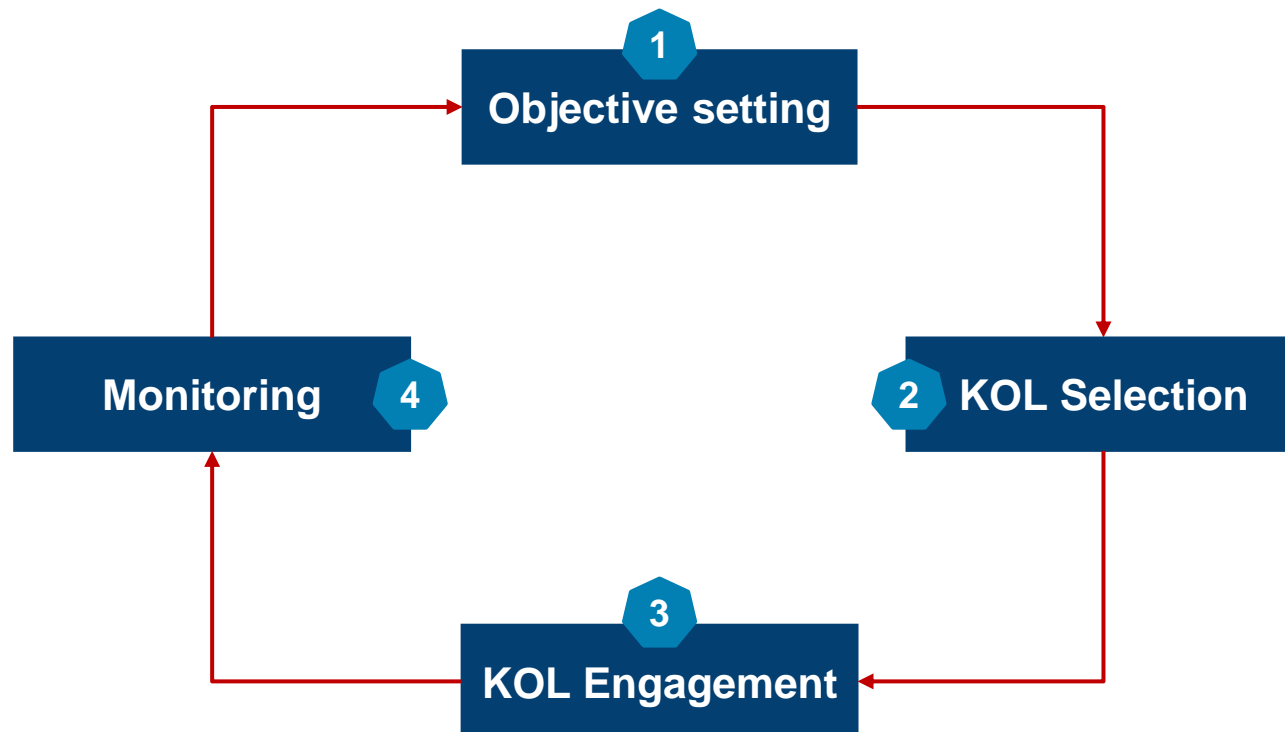


Sources: Best Practices, LLC (2014 & 2016) based on 33 companies, amongst which: AbbVie, Amgen, Bayer, Genentech, Genzyme, Janssen, Merck & Co, Pfizer, Roche – Smart Pharma Consulting analyses

¹ Whenever required by the compliance rules – ² Internal and external sources

The following 4-step approach is proposed to ensure an effective and efficient Strategic KOL Engagement Planning

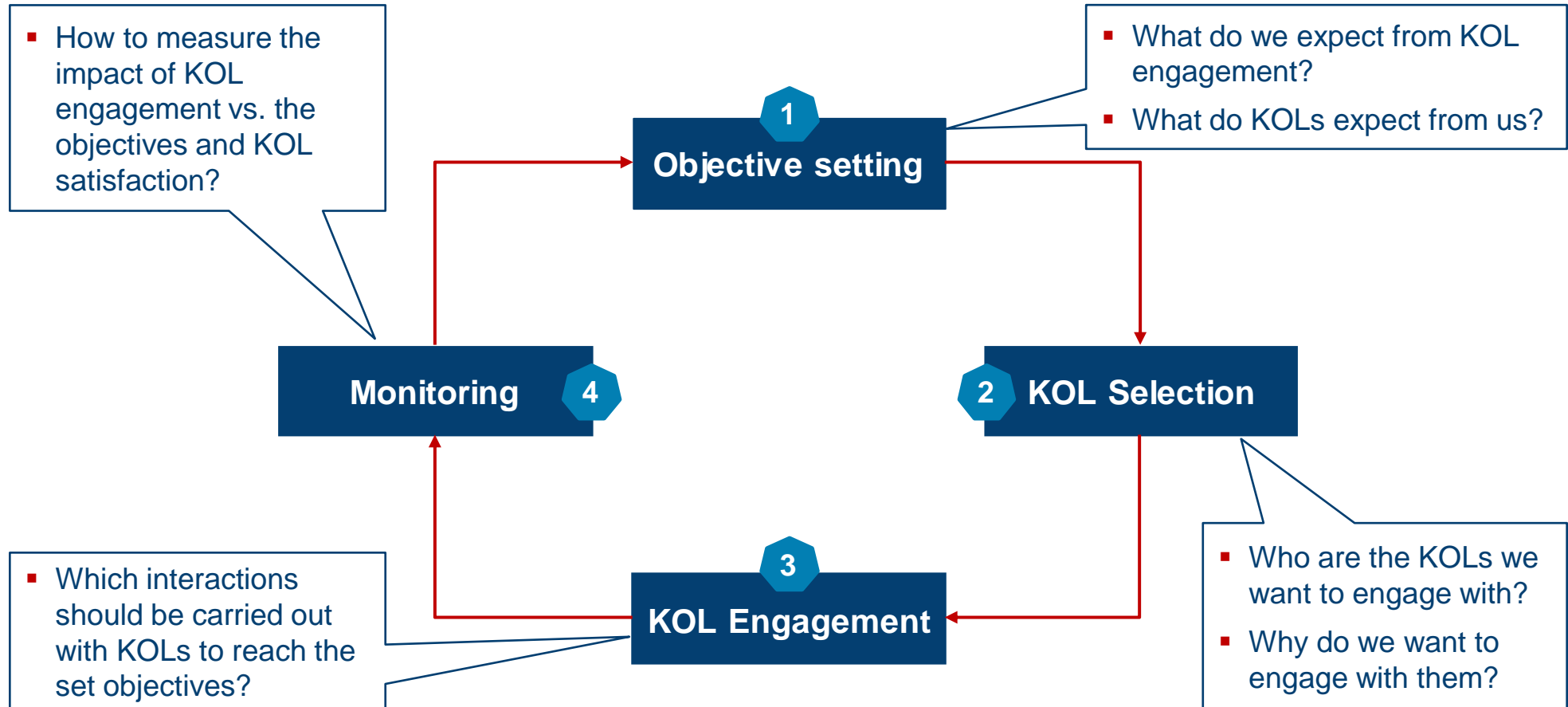
A 4-step approach



- 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 carry out should be **defined** and **formalized** in an **engagement plan**
- The **execution** of the plan should be carefully **monitored** with the help of **KPIs** (Key Performance Indicators) and of **KEIs** (Key Execution Indicators)

At each step, the following key questions should be carefully answered to ensure the proper implementation of the proposed Strategic KOL Engagement Planning process

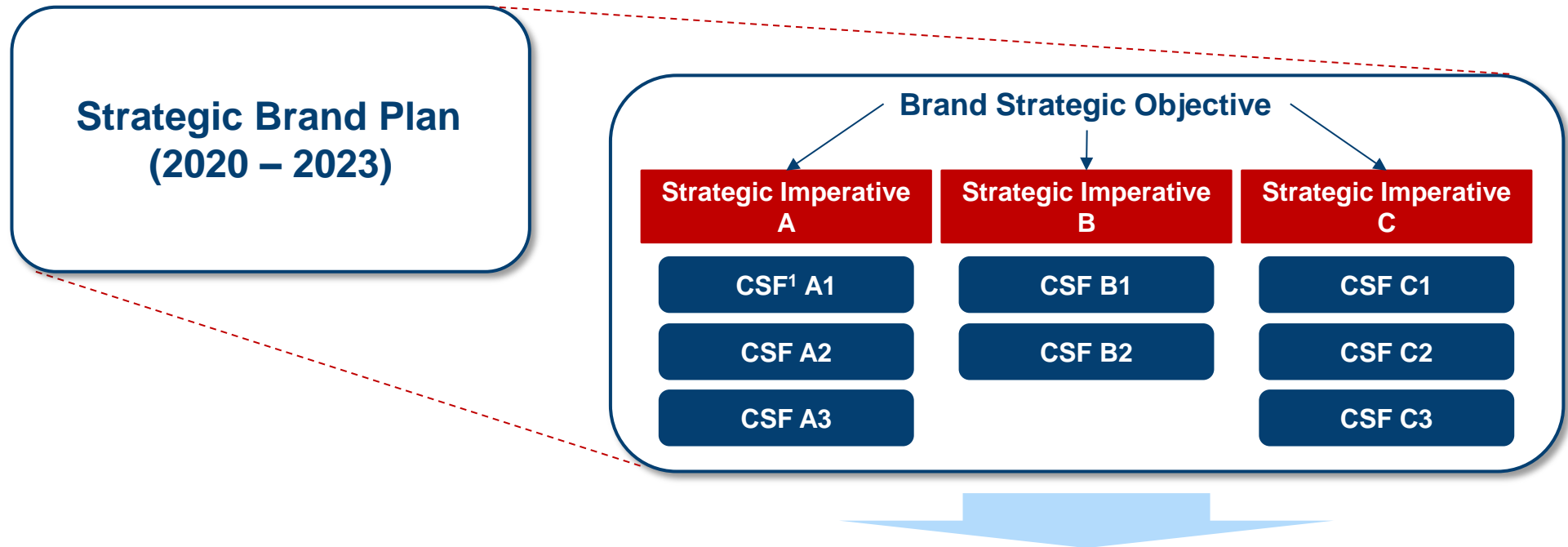
Key questions to be answered by key step



The global objectives set for KOL engagements should contribute – directly or indirectly – to meet the brand strategic objectives, irrespective of its life cycle position

1

Strategic alignment

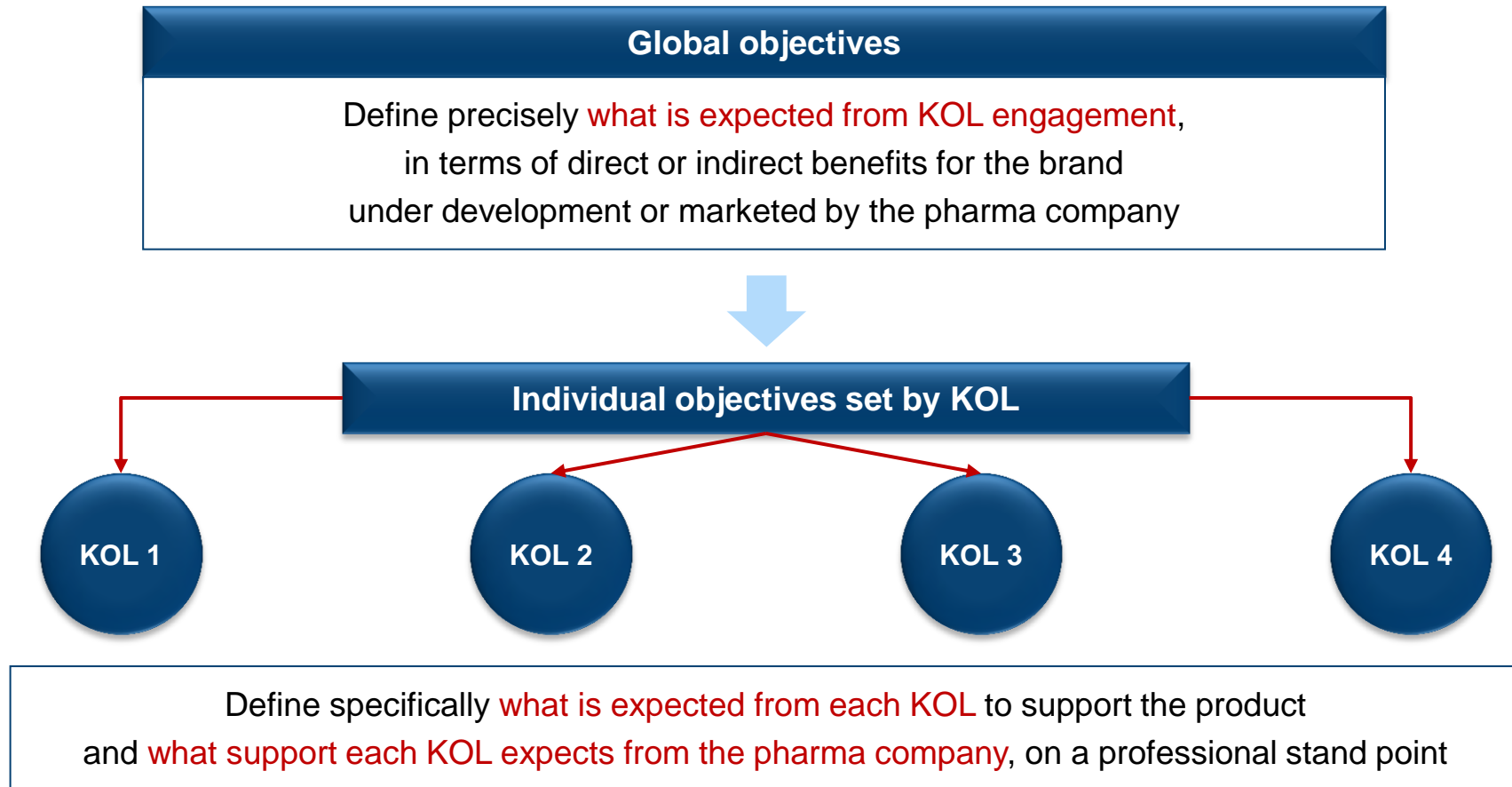


The global objective of KOL engagements must support one or several CSFs and thus, contribute to fulfill the strategic imperatives to reach the Brand Strategic Objective

Before defining the KOL Engagement Plan, specific objectives by KOL, consistent with the Brand Strategic Objective, must be set

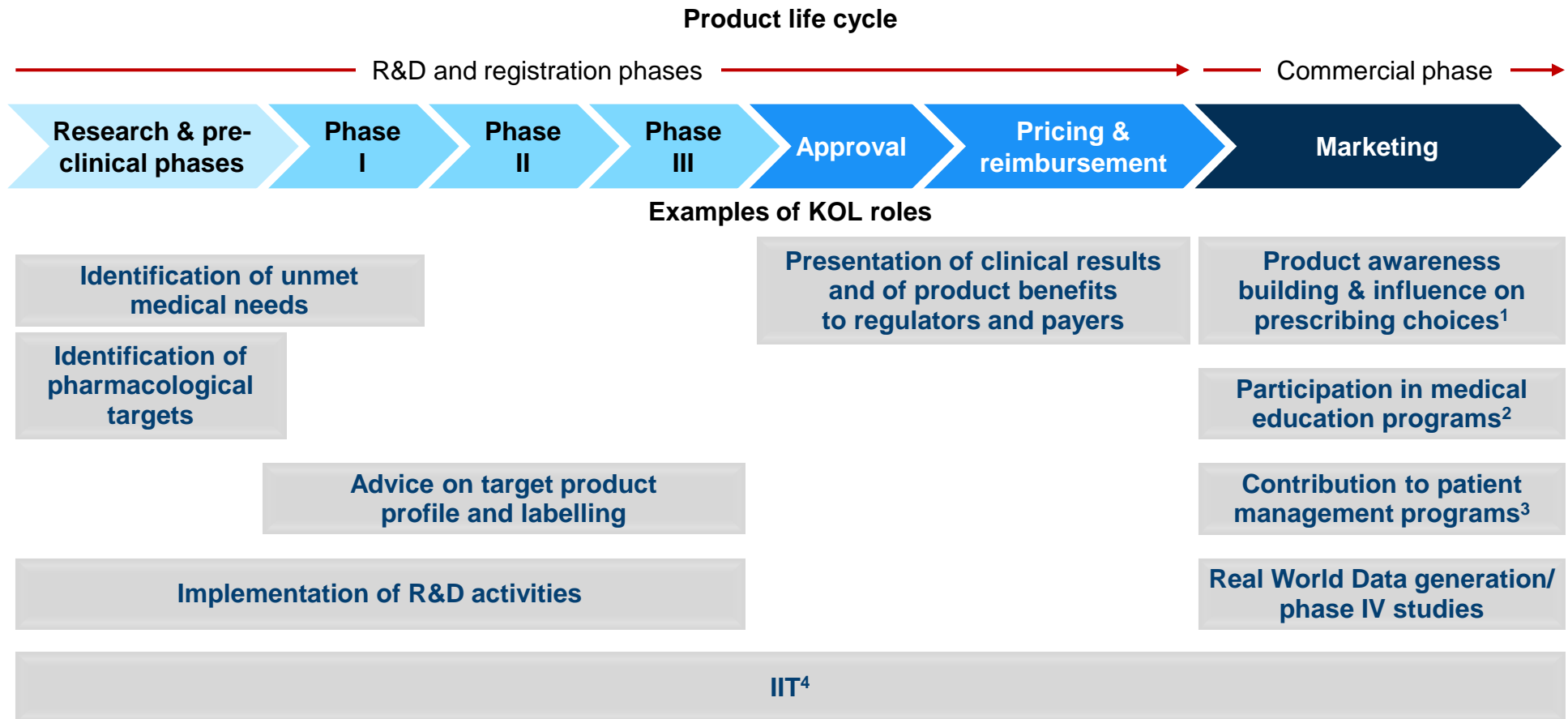
1

Global vs. individual objective setting



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 objectives along the product life cycle



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

¹ Through articles, lectures, etc. – ² Through Continuous Medical Education (CME) programs – ³ Through projects carried out with patient advocacy groups (PAGs) – ⁴ Investigator Initiated Trials

The selection phase consists in a 4-step process leading to a pool of KOLs with whom to engage to benefit (directly or indirectly) the brand

2

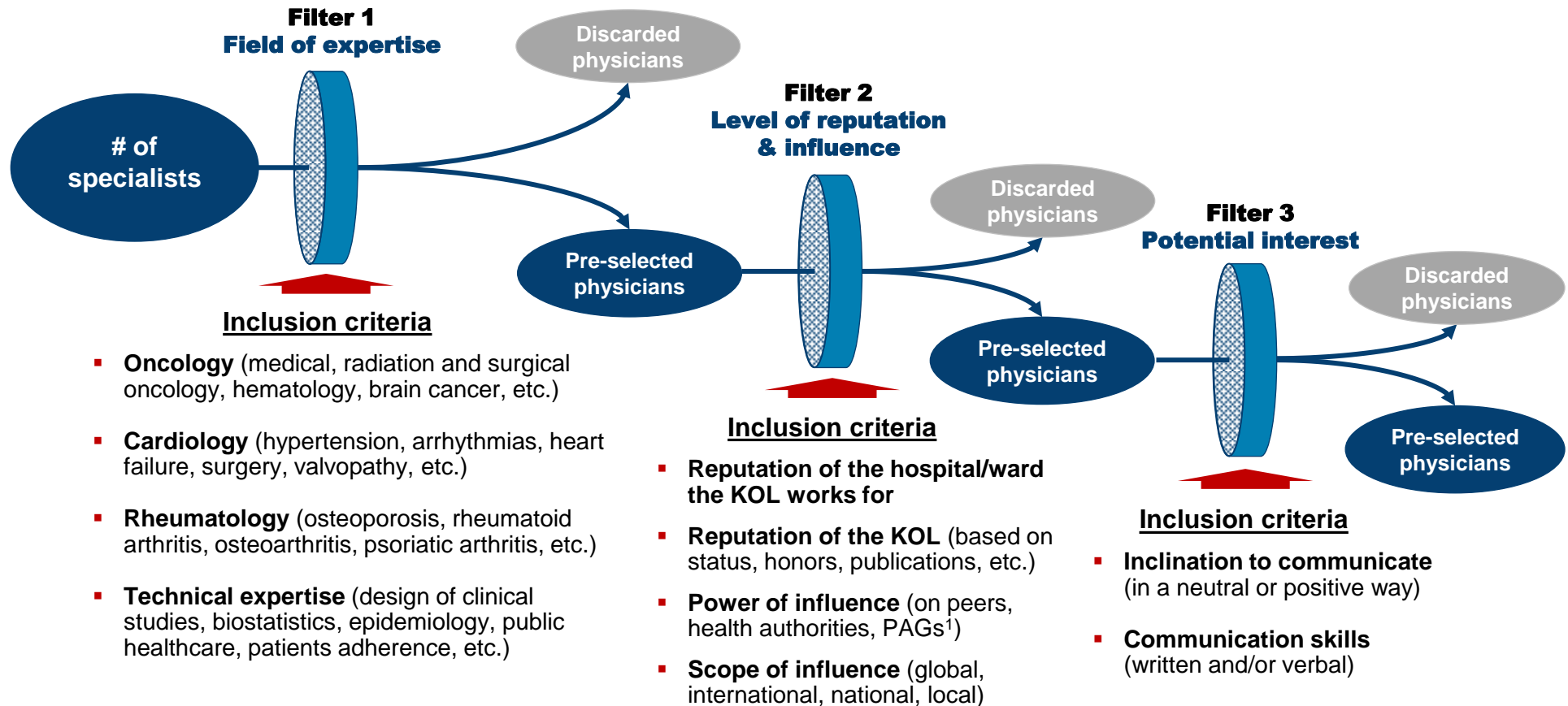
Methodology

	Key questions	What to do?
Selection criteria	<ul style="list-style-type: none"> What are the relevant selection criteria to be used considering the final objective? 	<ul style="list-style-type: none"> Review the relevant criteria (e.g. level of influence, scope of influence, scientific/media awareness, membership of a network, presence in Internet, etc.) Select a limited number of relevant criteria
KOLs profiling	<ul style="list-style-type: none"> What information should be collected? How to collect and analyze this information? 	<ul style="list-style-type: none"> Review internal / external databases to qualify KOLs Assess the number of publications, quality of journal, the impact factor, Almetrics¹, quotes, lectures during conferences and congresses, etc.
KOLs segmentation	<ul style="list-style-type: none"> What is the scope of influence and the degree of interest of the KOL for the brand and the related disease(s)? 	<ul style="list-style-type: none"> Map a preselection of KOLs on a matrix according to the most relevant criteria Identify KOLs networks of collaboration and influence (e.g. cooperative groups)
KOLs selection	<ul style="list-style-type: none"> Who are the KOLs that should be engaged? For which kind of engagement? 	<ul style="list-style-type: none"> Select the KOLs Preliminarily define the types of engagement to carry out with the selected KOLs

Relevant selection criteria and gathering of accurate and reliable information about the KOLs profiles are of utmost importance to optimize the value of their engagement

2

Screening process (illustrative)



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

2

How to qualify KOLs? (1/2)

What data to collect?	How to collect data?	How to analyze data?
<ul style="list-style-type: none"> ▪ Education (e.g. university – hospital) ▪ Medical activity/position (e.g. specialty, medical department, status in the medical department) ▪ Teaching activity/position (e.g. topics taught, professor, lecturer) ▪ Field of expertise and interest (e.g. specific disease, pharmacological route, mode of action, medical technique) ▪ Membership in learned societies (titles / positions / activities) and/or in more or less structured networks 	<ul style="list-style-type: none"> ▪ Internet search, direct search ▪ Field research (e.g. peers, hospital pharmacists interviews, etc.) ▪ Probing by collaborators from the medical department (e.g. MSLs¹) and collaborators from other departments of the pharma companies (data could be stored and shared on a platform) ▪ KOL Management vendors (e.g. Truven; KOL, LLC; OpenQ; Veeva Systems) 	<ul style="list-style-type: none"> ▪ Being head of hospital and professor is a plus ▪ Reputation of the hospital/teaching hospital or of the private institution where the KOL works should be considered ▪ Global or International scopes of influence are preferable, in general, to national or local levels (but it depends on the objective) ▪ Being a member of the management board of a learned society is a plus in terms of potential level of influence

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

2

How to qualify KOLs? (2/2)

What data to collect?	How to collect data?	How to analyze data?
<ul style="list-style-type: none"> ▪ Communication activities <ul style="list-style-type: none"> – # articles published (impact factor¹, Almetrics², peer-/non peer reviewed journals, principal investigator (PI), etc.) – # of training/teaching activities p.a. (CME³) – # of lectures (congresses, symposiums, round tables) – Presence on the Internet – # of quotes by journalists in current year 	<ul style="list-style-type: none"> ▪ Review of published scientific articles (PubMed/Medline, Google scholar, Expertscape, Cochrane Library) ▪ Evaluation of training/teaching activities and lectures by interviewing peers and collaborators of pharma companies ▪ Google searching for presence and quotes on the Internet 	<ul style="list-style-type: none"> ▪ The higher the impact factor is, the better ▪ KOLs should be ideally positioned as 1st or last author in articles ▪ A high number of training/teaching seminars and lectures is a plus ▪ The perceived quality of articles, training, teaching and lectures should be assessed
<ul style="list-style-type: none"> ▪ Partnership activities <ul style="list-style-type: none"> – Types of activities (e.g. lectures, clinical investigations, advisory boards) – With the company and its competitors – Potential level of interest (inclination to support the development/the proper use of a brand) 	<ul style="list-style-type: none"> ▪ Review of past performances with the company or its competitors (e.g. probing by collaborators of the company) ▪ Interviews of peers 	<ul style="list-style-type: none"> ▪ Verbal (e.g. lectures, courses) and written communication (e.g. articles, websites) ▪ KOLs should express their field of interest over the long term and their expectations from an engagement with the pharma company

Sources: Smart Pharma Consulting

¹ It measures the average frequency with which the article has been cited in a particular year. It is used to measure the importance or rank of a journal by calculating the number of times its articles are quoted – ² Collects and collates disparate information on the online activity surrounding scholarly content – ³ Continuous medical education

The following table shows a proposed approach to evaluate and rank candidate KOLs to set up a list of Top Global KOLs, that should be continuously updated

2

Scoring of candidate KOLs

Illustrative

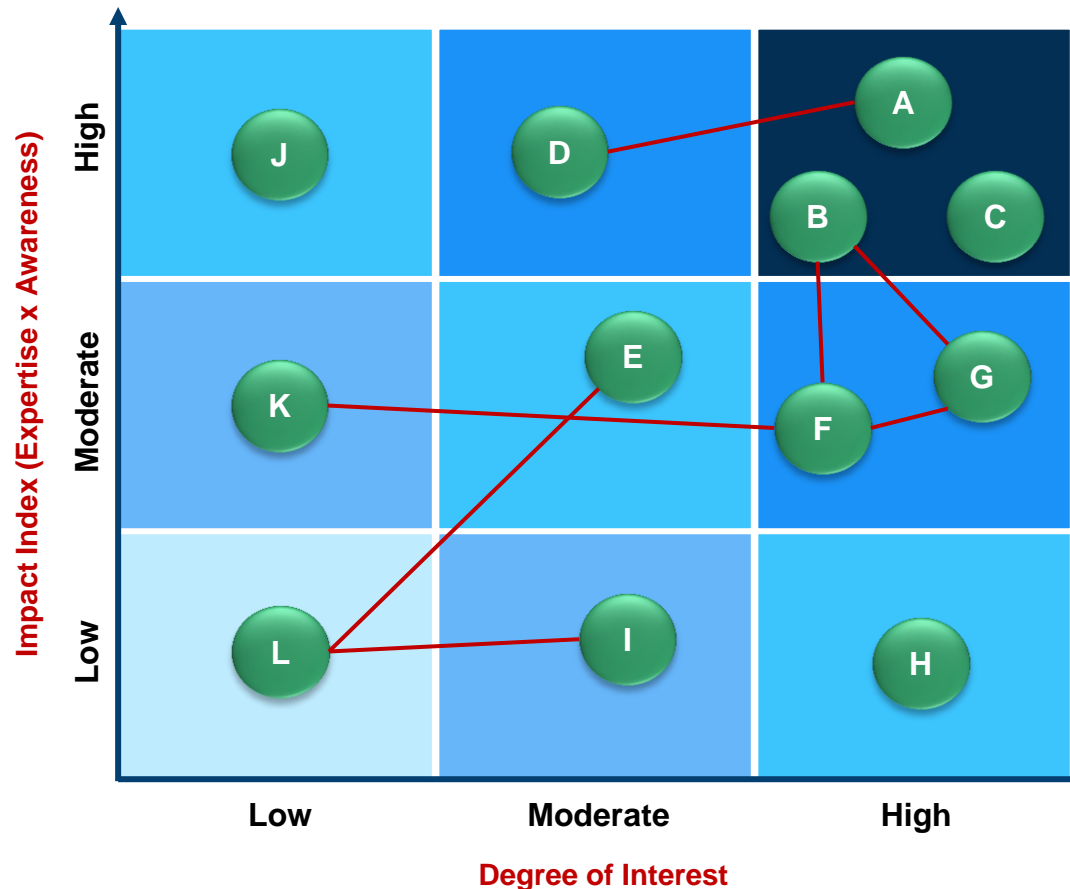
Profiling parameters		Prof. A	Prof. B	Prof. C	Dr. D
EXPERTISE	Pharmacological expertise	8	0	6	0
	Academic research	5	9	0	0
	Clinical research	5	0	9	5
	Clinical practice	0	0	6	9
	Scientific advisory board	8	8	7	6
	Sub-total score (A) ¹	5.2	3.4	5.6	4.0
AWARENESS	Publication record	8	5	4	3
	Speaker record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

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

The proposed matrix is a useful tool to prioritize the KOLs with whom to engage and to pre-define the types of collaboration to carry out with them

2

KOL targeting – Segmentation & selection



- The proposed matrix facilitates the **final selection** (targeting) of pre-selected KOLs based on their:
 - **Impact index** (combining their degree of expertise and awareness¹)
 - **Potential interest**
- The **impact index** reflects the KOLs **ability to influence** other stakeholders (i.e. HCPs, policy makers, payers, patients, PAGs)
- The **degree of interest** reflects the KOLs **willingness to support**:
 - The **development** of the company **brand**
 - The proper **use of the brand**, once marketed
- The **network**² of KOLs should also **be considered**

Priority 1 Priority 2 Priority 3 Not a Priority

— Networks of influence / collaborations amongst KOLs

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

2

How to convince KOLs to partner?

What do KOLs want through engagements?

- The selection of KOLs should consider the **benefits they can offer** to the pharma companies and the **benefits** the pharma **companies** can **offer to them**
- *For so doing, the following questions should be addressed:*
 - Is the KOL **yet a partner** of the pharma company?
 - What has been qualitatively and quantitatively **his level of involvement?**
 - What has been **his feed-back** (level of satisfaction) from previous collaborations?
 - What is his mid- to long-term professional **ambition?**
 - What does **he expect from collaborations** with pharma companies?
 - Is he looking for a long-term partnership or a “fee-for-service” transaction?

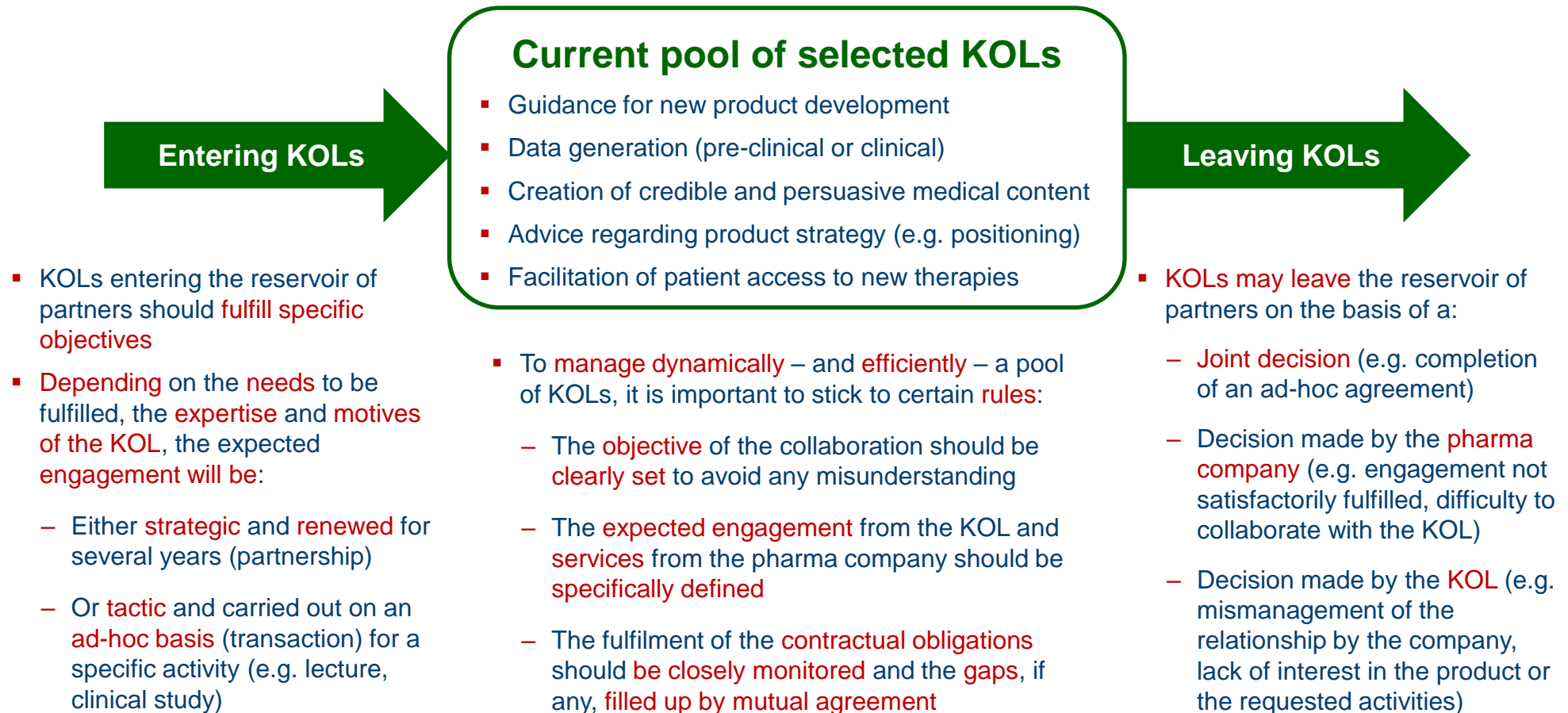
What should pharma companies propose to KOLs?

- Based on KOLs professional expectations, pharma companies can **propose ideas** of “**win-win**” **activities** to be carried out through engagements
- The **benefits** the **KOLs** will draw in terms of **personal awareness** and **competence development** through the engagement should be **emphasized**:
 - **Opportunity to participate in publication** of articles, **interviews** in media, **presentations** during congresses, lectures during medical meetings, etc.
 - **Provide expert opinion/guidance and/or...**
 - **... opportunity to participate in clinical research (e.g. clinical trials) or to carry out IITs¹**
 - **Professional development** through the **access to recent information**, to **high education programs²**, by working in **new research/medical areas**, etc.

Pharma companies should be able to manage dynamically their selected KOLs by attracting newcomers and putting an end to some existing collaborations

2

Dynamic management of selected KOLs

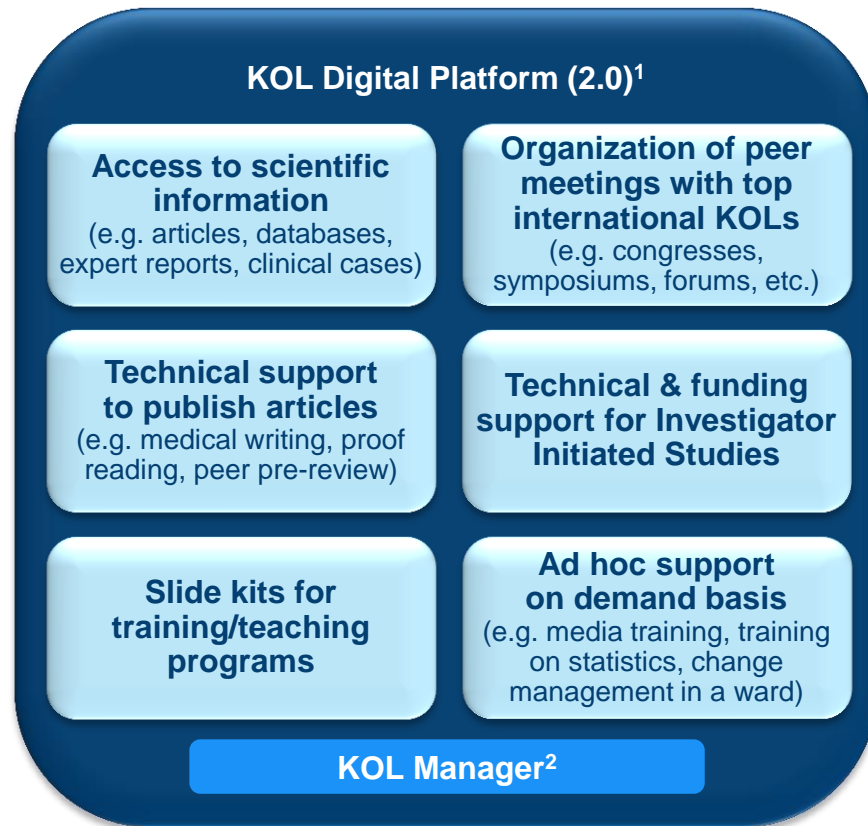


Pharma companies should balance what they expect from KOLs in terms of activities and what they give them in terms of services to ensure a win-win partnership

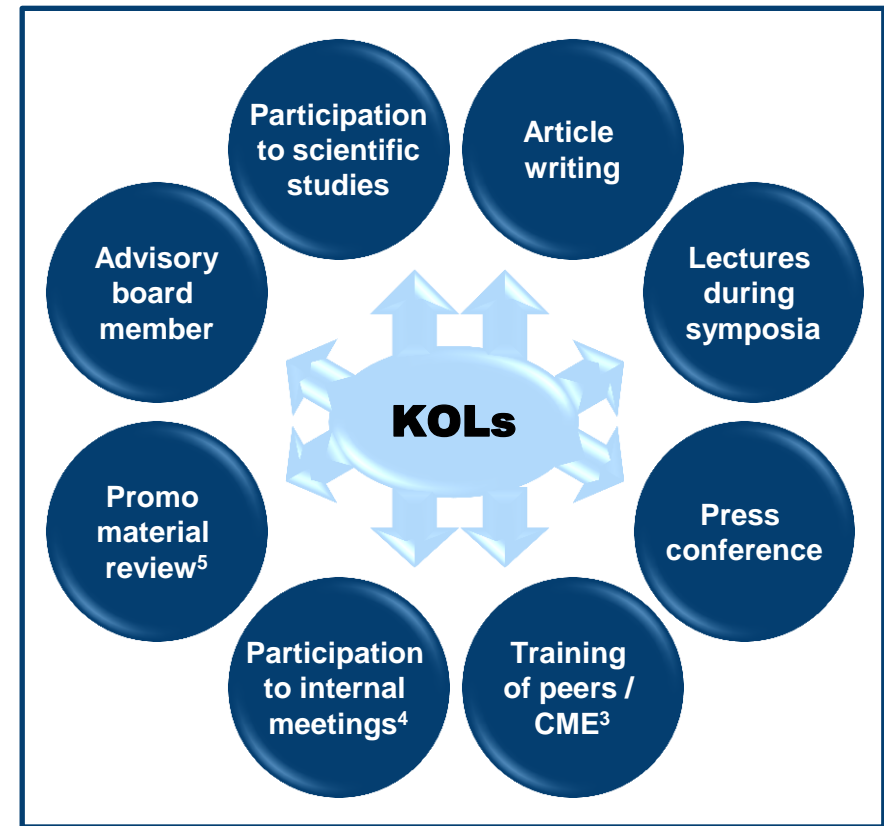
3

Services proposed to & activities carried out by KOLs

Services proposed to KOLs (Illustrative)



Activities carried out by KOLs (Illustrative)



Sources: Smart Pharma Consulting

¹ Access limited to KOLs – ² Each KOL should have a dedicated KOL Manager (e.g. a MSL) – ³ Continuous Medical Education – ⁴ Such as lectures to sales forces, face-to-face meetings with the marketing team, etc. – ⁵ Such as visual aids, leaflets for patients

If KOLs share the objective of the pharma company and accept to communicate, the following means can influence medical practices and help better position products

3

Potential value of KOL activities (1/2)

Article writing

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

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

Lectures during symposia

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

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

Press 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: **M-H***

Training of peers / CME¹

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

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

H: Higher – M: Medium – L: Lower

KOLs can be of great value through direct collaboration (by training, informing, giving advice, etc.) with medical and marketing 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 teams about scientific trends and position of competitors
 - Being invited as a “guest star” to show collaborators the ability of the pharma company to partner with top medical leaders
 - Playing a role with sales reps (e.g. selling forums)

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

Advisory board member

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

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...)

A comprehensive KOL engagement strategy requires from pharma companies to gain an in-depth understanding of KOL challenges, motivators and expectations

3

KOLs challenges – motivators – expectations

Challenges

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

Motivators

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

Expectations from pharma companies

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

“One goal that most KOLs share is to capture attention and prestige within their community”

In general, the most common criticisms by KOLs at pharma companies are related to absence of true partnerships and of cohesive internal strategy and processes

3

Top 10 poor pharma companies practices & key learnings

Top 10 poor practices

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



Key learnings

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

The development of a KOL Engagement Plan is a centerpiece to maximize the probability of success while partnering with KOLs

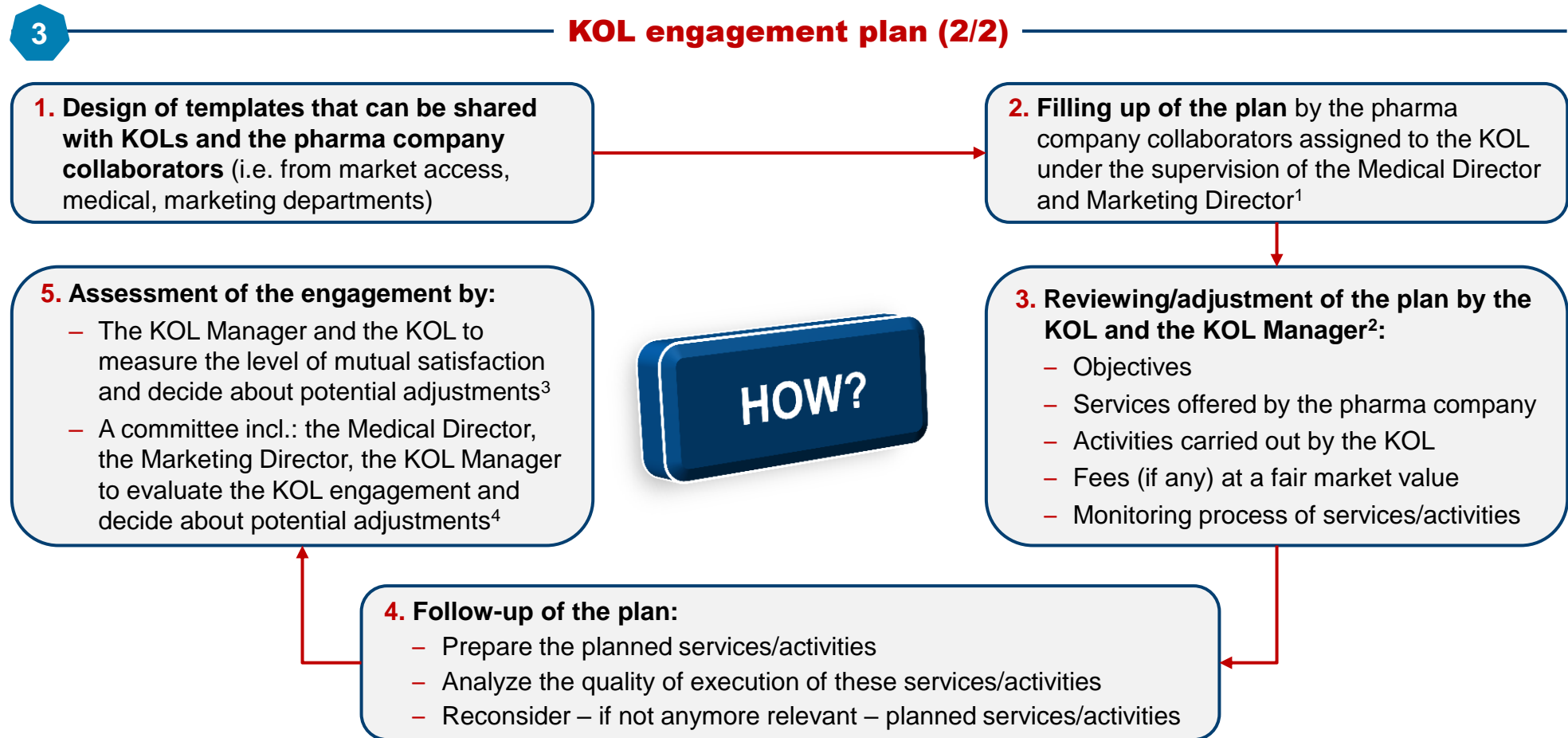
3

KOL engagement plan (1/2)

WHY?

- The development of a clear – precise – concise and shared engagement (activity) plan, between KOLs and pharma companies – will ensure that:
 - Objectives of collaboration are well understood and agreed upon
 - Reciprocal expectations are well defined and accepted
 - Respective commitments are fulfilled and in due time
- The preparation of an engagement plan increases the probability of success of the partnership over time...
- ... and minimizes the risks of mutual disappointments
- The KOL Engagement Plan (KEP) will facilitate the coordination and the communication across the pharma company and thus optimize synergies across market access, medical and marketing departments

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

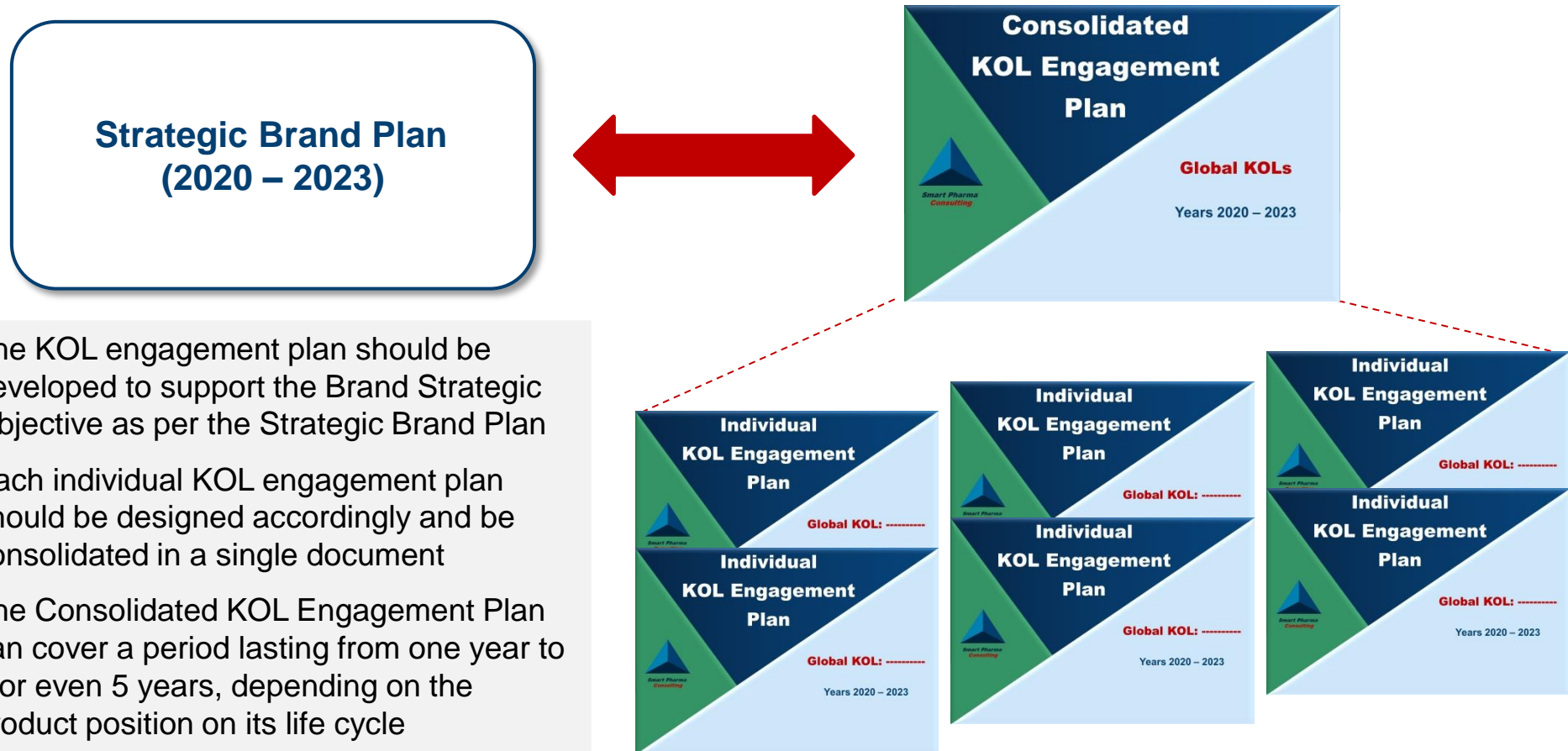


“To find common ground is a key success factor in KOL engagement”

Individual KOL Engagement Plans should be co-developed by the KOL and the pharma company to avoid any misunderstanding and subsequent disappointments

3

Development of KOL Engagement Plans



The KOL Engagement Plan should be formalized in a document that could be structured as proposed in the table of contents, here-below

3

Structure of a Consolidated KOL engagement plan

Illustrative



Table of Contents

- Introduction
 - Brand Strategic objective (vision)
 - Brand Strategic Imperatives & Critical Success Factors
 - Brand development priorities (3-year perspective)
- Expected contribution from the pool of Global KOLs
- Expected contribution from individual Global KOLs
 - Type of agreement (ad-hoc, partnership, duration, etc.)
 - Key activity selection (e.g. advisory board meeting, lecture, clinical study, peer-to-peer trainings)
 - Key activity description (e.g. objective, timing, accountability, budget)
 - Key activity monitoring (e.g. KPIs¹ and KEIs²)

The KOL Engagement Plan should include key information extracted from the KOL database, specify the objectives of the collaboration, its scope and duration

3

Individual KOL engagement plan – ID Card

Illustrative

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

Primary objectives of the collaboration				
Specific activities planned within the engagement¹				
Type of agreement		Duration of the agreement		
• Transactional agreement:		• Annual:	from: ---/---/---	to: ---/---/---
• Partnership agreement:		• Multi-year:	from: ---/---/---	to: ---/---/---

The KOL Engagement Plan should describe the activities the KOL is engaged to carry out to meet specific objectives, and it should include monitoring indicators

3 4

Individual KOL Engagement Plan – KOL Activity Card

Illustrative

KOL Activity	<ul style="list-style-type: none"> Lecture, training of peers, advisory board, press conference, article writing, IIS, clinical study, etc. 	Objectives	•	Pharma company contact point	
---------------------	--	-------------------	---	-------------------------------------	--

Key implementation steps	Timing	Points of caution	Expected output / value of the activity for...		
•		•	... the KOL herself/himself	... the pharma company	... 3 rd parties -----
•		•	•	•	•
•		•			
•		•			
•		•			

Feasibility (High – Moderate – Low)		Key Execution Indicators		Key Performance Indicators	
Technical	•	• These indicators measure the quality of execution of the activity		• These indicators measure the impact (output/value/benefit) of the activity for the different targets (the KOL, the pharma company and possibly for 3 rd parties, like peers, patients, PAGs)	
Regulatory	•				
Financial	•				

Sources: Smart Pharma Consulting

The KOL Engagement Plan should also describe, plan and follow up the services proposed to the KOL, as a constituent of the partnership-based agreement signed

3 4

Individual KOL Engagement Plan – Partnership-based Service Card

Illustrative

Pharma company services	<ul style="list-style-type: none"> Access to scientific information, technical support to publish articles, provision of training/teaching materials, organization of peer meetings, etc. 	Objectives	•	Pharma company contact point	
-------------------------	--	------------	---	------------------------------	--

Key implementation steps	Timing	Points of caution	Expected output / value of the service for...	
•		•	... the KOL herself/himself	... the pharma company
•		•	•	•
•		•		
•		•		
•		•		

Feasibility (High – Moderate – Low)		Key Execution Indicators		Key Performance Indicators	
Technical	•	<ul style="list-style-type: none"> These indicators measure the quality of execution of the service provided to the KOL 		<ul style="list-style-type: none"> These indicators measure the impact of the service provided to the KOL 	
Regulatory	•				
Financial	•				

Sources: Smart Pharma Consulting

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

4

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

KOLs activities	Key execution indicators (KEIs)	Key performance indicators (KPIs)
<ul style="list-style-type: none"> Lecture during symposia or congresses 	<ul style="list-style-type: none"> Interest (10-point scale) Utility (10-point scale) 	<ul style="list-style-type: none"> Global level of satisfaction of attendees (10-point scale) Inclination of attendees to support & prescribe the product: <ul style="list-style-type: none"> Number of lectures/trainings/publications Quality/objectivity of messages conveyed to peers, pharmacists, PAGs, etc.
<ul style="list-style-type: none"> Training of peers 	<ul style="list-style-type: none"> Practicality (10-point scale) Implementation¹ (10-point scale) 	
<ul style="list-style-type: none"> Article writing 	<ul style="list-style-type: none"> Acceptance by recognized journals (scientific, medical, or in lay press, etc.) Post on highly regarded websites 	<ul style="list-style-type: none"> Impact factor and Altmetrics² (for scientific / medical journals) Number of broadcasted issues for lay press
<ul style="list-style-type: none"> Press conference 	<ul style="list-style-type: none"> Number and quality of press conferences conducted 	<ul style="list-style-type: none"> Number of views / likes on Internet Contribution of content to support the product
<ul style="list-style-type: none"> Participation in scientific studies 	<ul style="list-style-type: none"> Implementation (number of patients recruited, timing, actual costs vs. budget) 	<ul style="list-style-type: none"> Publication of an article in a renowned scientific journal Impact of the publication on product reputation

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

4

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

Pharma company services	Key execution indicators (KEIs)	Key performance indicators (KPIs)
<ul style="list-style-type: none"> Access to scientific information 	<ul style="list-style-type: none"> Interest (10-point scale) Utility (10-point scale) Practicality (10-point scale) Implementation² (10-point scale) 	<ul style="list-style-type: none"> Global level of satisfaction of KOLs (10-point scale) Inclination of KOLs to support the pharma company products: <ul style="list-style-type: none"> Number of lectures / trainings / publications Quality/objectivity of messages conveyed to peers, pharmacists, patients, etc. Increased level of KOLs awareness and reputation Increased level of products awareness and reputation
<ul style="list-style-type: none"> Organization of peer meetings with top global / international KOLs 		
<ul style="list-style-type: none"> Publications support 		
<ul style="list-style-type: none"> IIT¹ support 		
<ul style="list-style-type: none"> Slide kits for training / teaching programs 		
<ul style="list-style-type: none"> Ad hoc support on demand basis 		

Future trends *in KOL Engagement Planning*

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

Recommendations *for a Successful KOL Engagement Planning*

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

*Define **internal guidelines** and a **control process** to prevent any **compliance issues** that could damage your corporate reputation*

The Smart Manager *Series* (#4)

Excellence in Execution ...

**Key principles
&
Tools**

**... Applied to
Pharma Companies**

June 2019



**Smart Pharma
Consulting**

*"Excellence is not a skill.
It is an attitude"*

– Ralph Marston

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1. Introduction

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

- If the quality of R&D remains the primary success driver of innovative pharmaceutical companies, the quality of their medical, marketing and sales departments is also of utmost importance to turn new products into commercial successes
- Actually, the great majority of drugs face strong competition, which requires the crafting of a solid medical, marketing and sales strategy to boost customer preference and hence optimize corporate revenues
- However, business successes or failures are more dependent on the quality of the strategy execution than on the chosen strategy
- The purpose of this position paper is to propose principles and practical recommendations to help pharma companies excel in executing their strategy

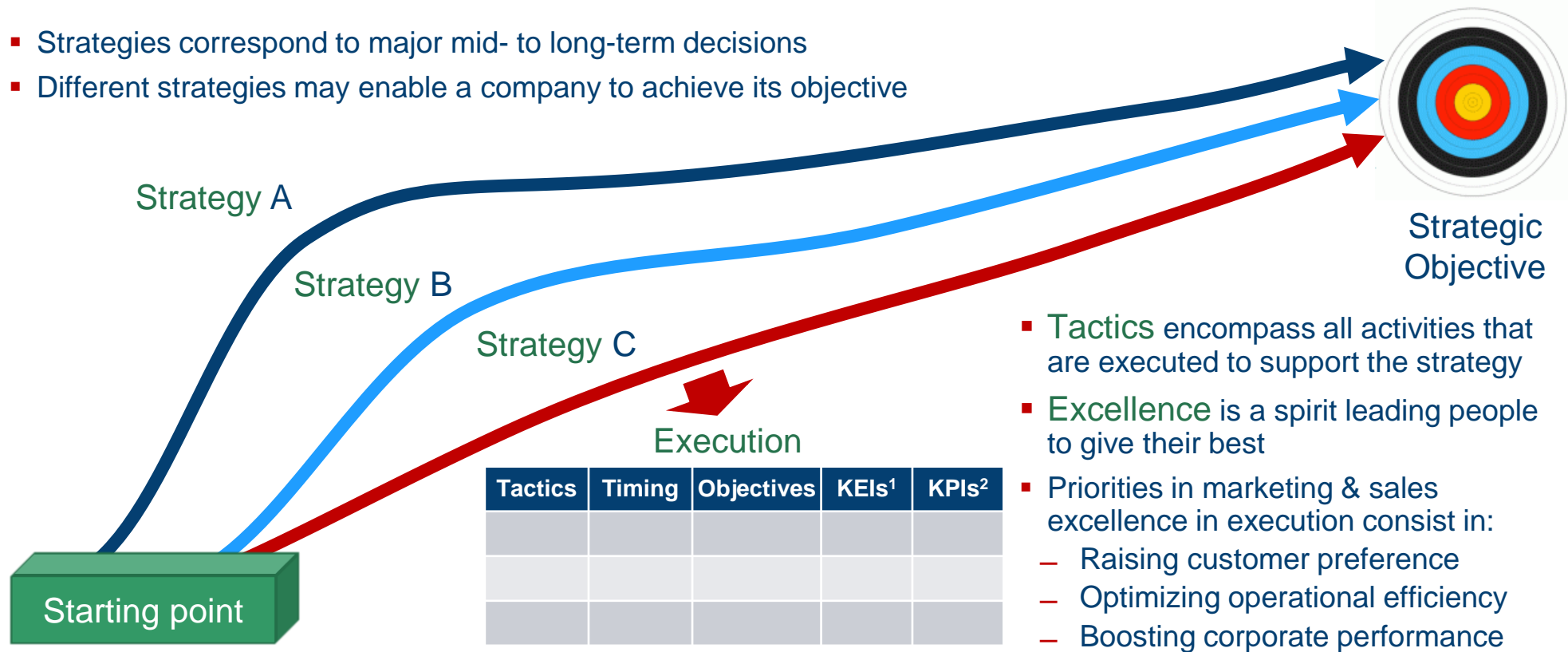
“Strategy is about execution” – Sanjiv Anand

1. Introduction

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

Strategy – Tactics – Execution – Excellence

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



1. Introduction

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

The Smart Strategic Model™ – Principles



- **Purpose:** Why do we exist?
- **Vision:** What do we aspire to become?
- **Mission:** What do we do and for who?
- **Values:** What do we believe in and how do we behave?
- **Objective:** What do we want to achieve?

- **Strategy:** Where to play and how to play to win?
- **Organization:** What activities, processes, structure¹ and culture we put in place to execute the strategy?
- **Key tactics:** How are we going to execute the strategy?
- **Performance:** What have we quantitatively and qualitatively² achieved and what are the gaps and why, if any?

1. Introduction

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

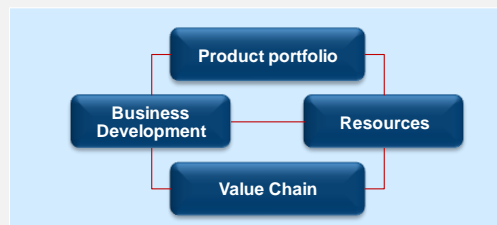
The Smart Strategic Model™ – Strategy & Organization

Situation & Trends Analysis

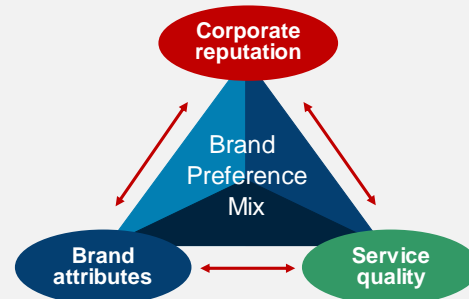
Competitive Landscape Analysis



Company Assets Assessment



Strategy Crafting

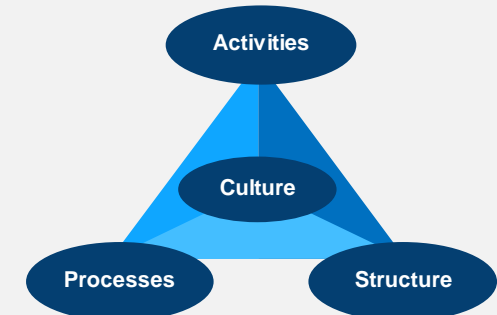


Marketing & sales strategies should be crafted to raise customer preference and create a long-lasting competitive advantage by:

- Seizing market opportunities
- Combating market threats
- Leveraging competitive strengths
- Addressing competitive weaknesses

Strategic Objective

Organization Design



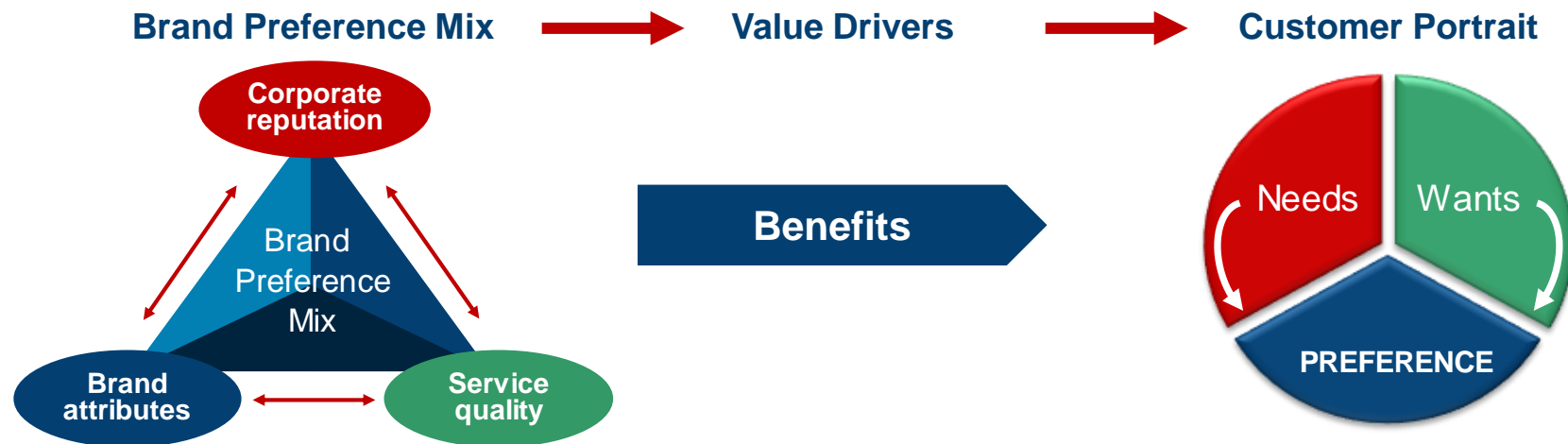
The organization should be designed to support the crafted strategy efficiently. Four dimensions should be considered:

- Activities (and competencies)
- Structure (FTEs, organization chart)
- Processes (coordination, decision-making, information sharing, etc.)
- Culture (working conditions, etc.)

1. Introduction

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

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



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

Customer preference is **driven by** their:

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

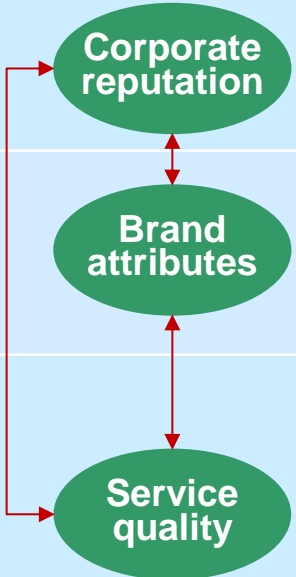
But **limited by** their:

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

1. Introduction

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

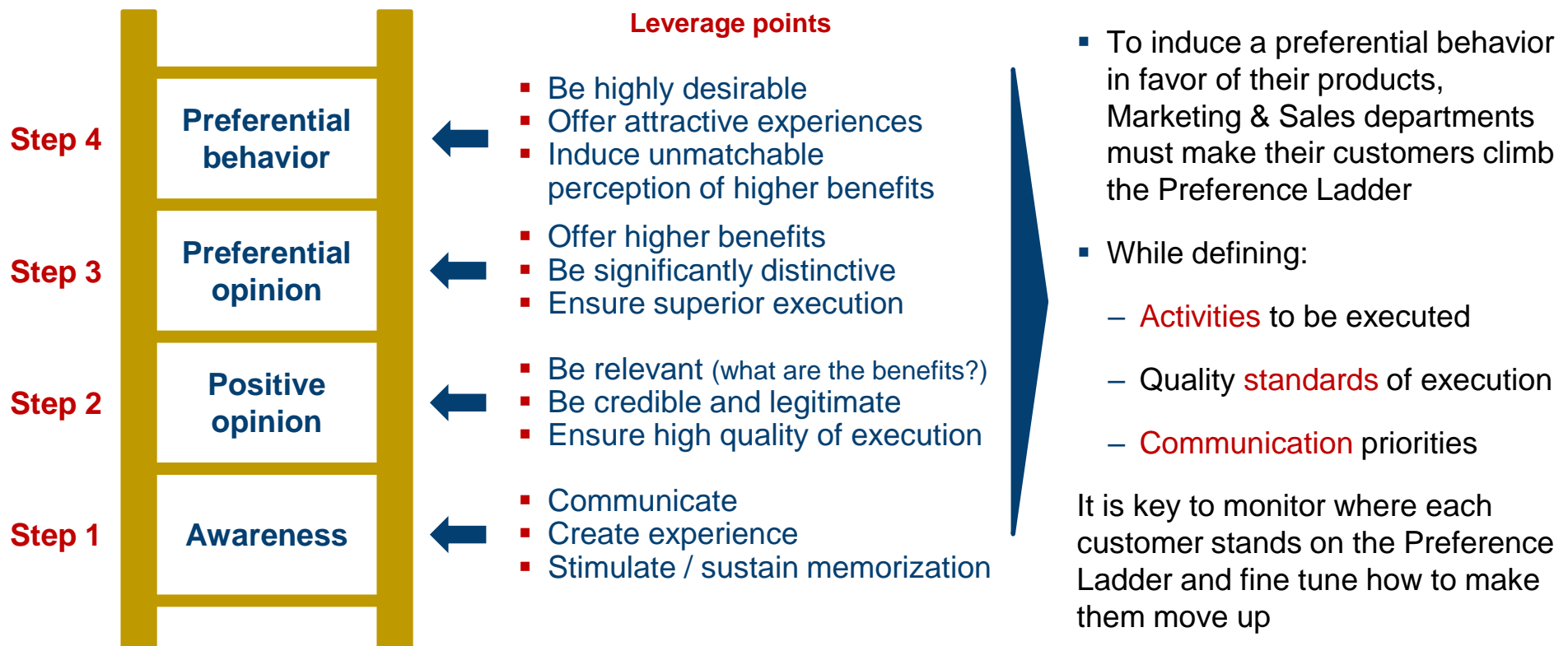
The Smart Strategic Model™ – Key Tactics (2/2)

Brand Preference Mix (BPM)	Features of the BPM pillars	Benefits to customers
 <p>Corporate reputation</p> <p>Brand attributes</p> <p>Service quality</p>	<ul style="list-style-type: none"> What to say and do to build an appealing image and establish the company as a reliable player? How should these initiatives be carried out? 	<p>The benefits the customers are likely to draw¹ should be identified for each feature of each component of the Brand Preference Mix</p>
	<ul style="list-style-type: none"> How to differentiate positively the brand from competition? How to highlight these attributes in an effective and efficient way? To whom these differentiating points should be communicated? 	
	<ul style="list-style-type: none"> What services to develop to create a superior difference vs. competition? How to make sure these services are highly valued by customers? <i>[Are they useful / interesting / convenient / well executed?]</i> How should these services be executed to meet excellence? 	

1. Introduction

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

The Smart Strategic Model™ – Expected Outcomes



1. Introduction

Strategy and execution must be perfectly aligned to lead to success

Strategy to Execution Alignment



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



Case study: Starbucks



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

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

2. Definitions

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

Excellence vs. Perfection

EXCELLENCE



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

~~PERFECTION~~



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

“Strive for excellence, not perfection”

3. Why is Excellence in Execution so Important?

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



Excellence in Execution

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

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

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

4. Reasons for Poor Execution in the Pharma Industry

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

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

#1

Brand strategy crafted at the global level is not necessarily relevant to local markets

#2

Unclear understanding of the brand strategy by medical, marketing and sales people

#3

Insufficient customer insights (knowledge and understanding of their wants and needs)

#4

Poor quality of interactions with HCPs which are seen as useless and not interesting

#5

Inefficiency of first line managers to develop frontline collaborators competence¹

#6

Low enthusiasm from medical, marketing and sales teams who are insufficiently connected

#7

Activities carried out without prior evaluation of their likely impact on customers

#8

Non systematic evaluation of the impact of key activities on customer level of preference

#9

Suboptimal collaboration and cooperation between medical, marketing and sales teams

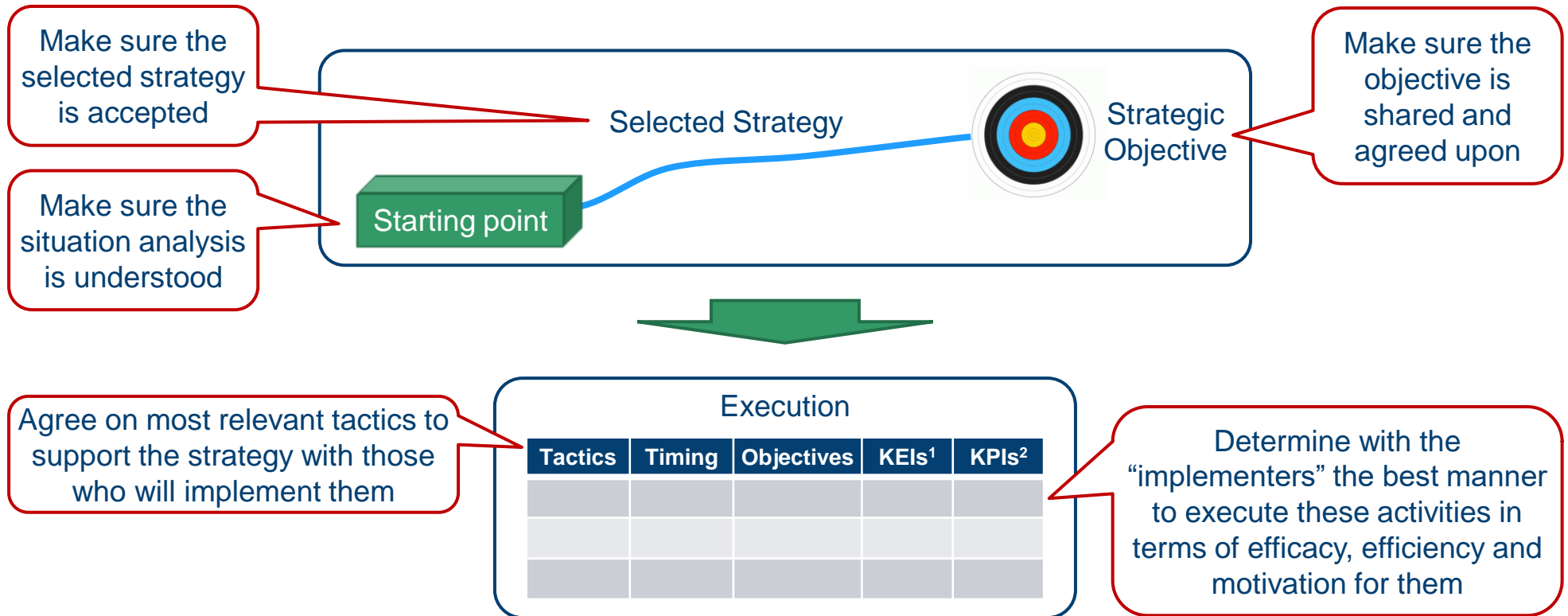
#10

Lack of boldness from the regulatory department to accept innovative ideas

5. How to develop a Smart Execution Excellence Model?

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

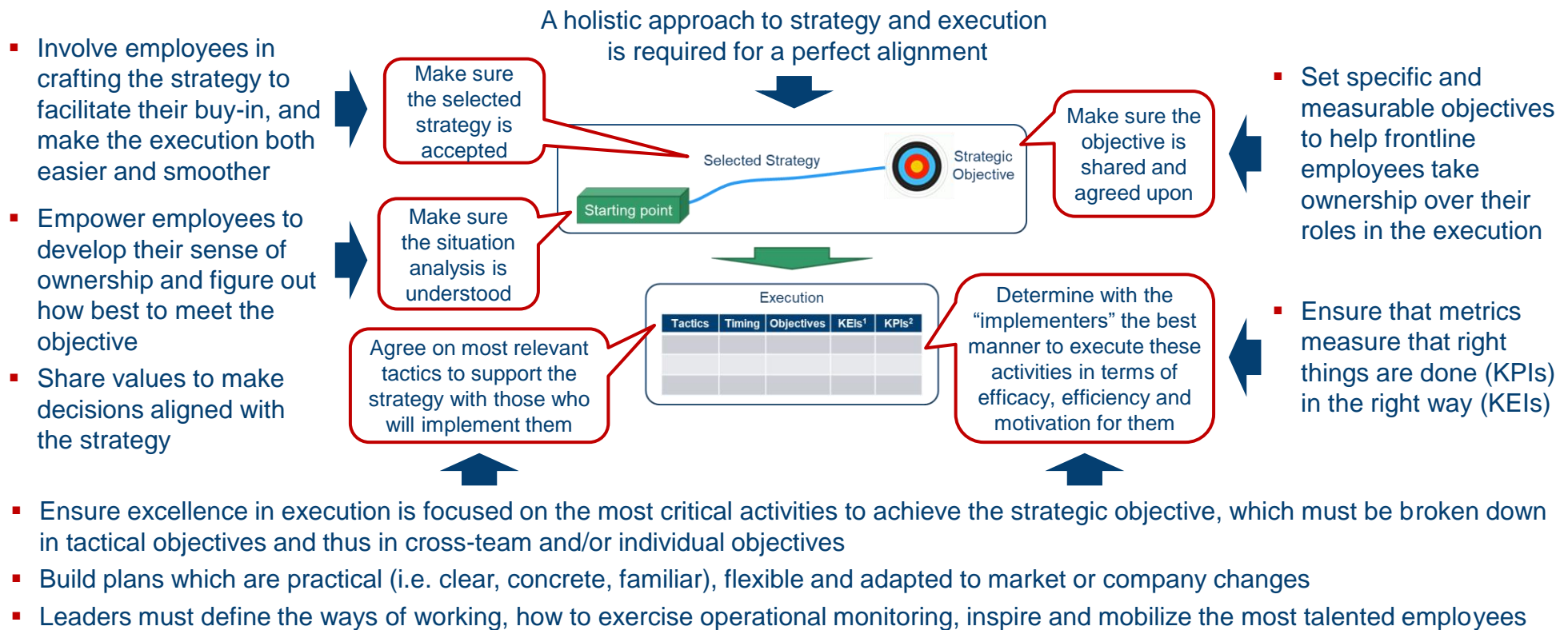
Introduction (1/2)



5. How to develop a Smart Execution Excellence Model?

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

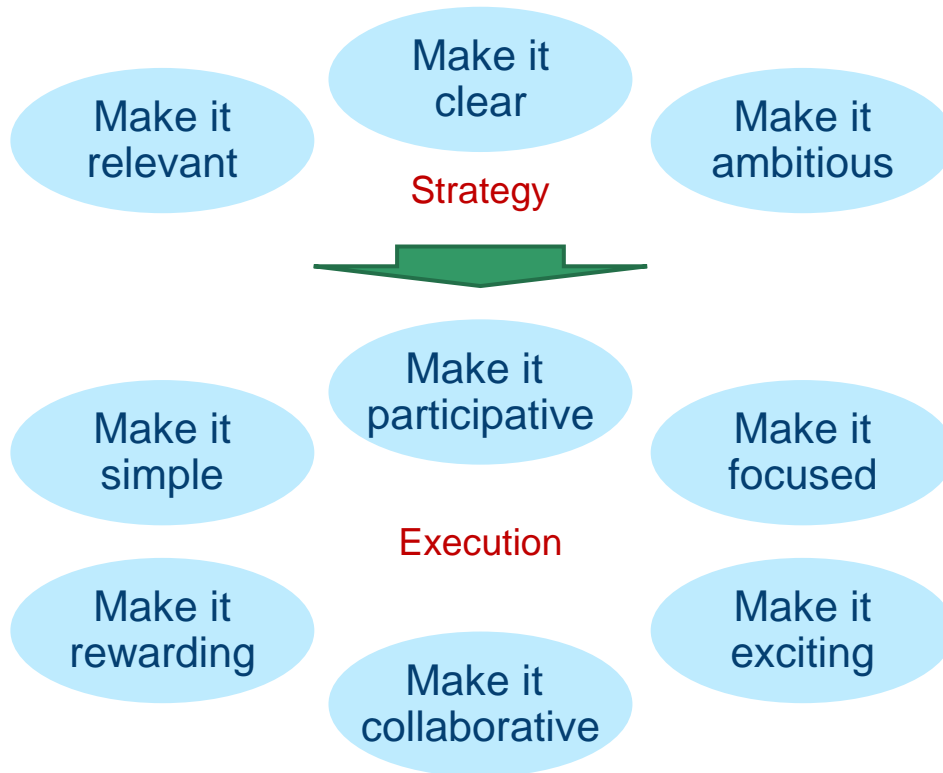
Introduction (2/2)



5. How to develop a Smart Execution Excellence Model?

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

Nine guiding principles



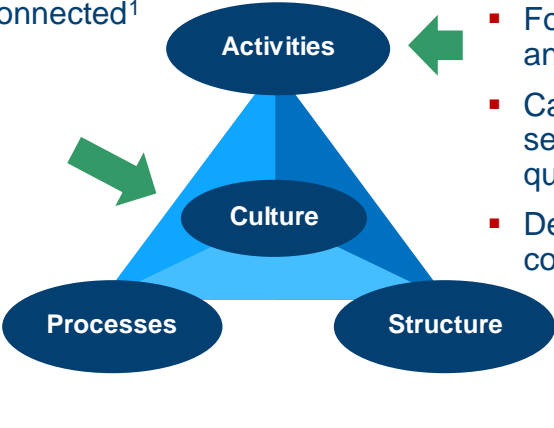
Five key execution-related questions

- 1. What to do?**
Select the most relevant activities
- 2. Why to do it?**
Document the rationale to carry out these activities
- 3. How to do it?**
Define the best practices and the best organization
- 4. How well it has been done?**
Monitor the quality of execution
- 5. How close are we from the objective?**
Monitor the performance

5. How to develop a Smart Execution Excellence Model?

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

Key organizational recommendations

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

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

¹ Set clear performance expectations, hold them accountable, give them regular feedbacks, reward their performance, share outcomes, etc. – ² Solicit ideas and inputs, listen to people, select and implement their most appropriate suggestions

6. Case Study: The Mumbai Dabbawalas

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

Description of the Business Model (1/2)



Dabbawala in Mumbai area

- The dabbawalas deliver ~130,000 lunchboxes per day, in Mumbai area, from homes and restaurants to people at work
- The lunchboxes are picked up in the morning, delivered predominantly using bicycles and railway trains by 1:00 pm



Lunchboxes distribution by handcarts

- Lunchboxes are labeled using a system of signs symbols, numbers, letters and colors indicating:
 - Where the lunch has been picked up
 - Which station it will be sent to
 - The final address of the owner
- This old-fashioned distribution system is more effective than Deliveroo or Uber Eats
- It is recognized as one of the world's most efficient logistics systems



Lunchbox coding system

- The cost for the service is ~ € 6 per month
- The dabbawalas belong almost exclusively to the Varkari community, which worships the Hindu god Vithala who teaches that “giving food is a great virtue”
- They are organized in a cooperative of 5,000 semiliterate partners, are self-employed and paid the same, around € 190¹ per month, and receive in addition tips from their customers

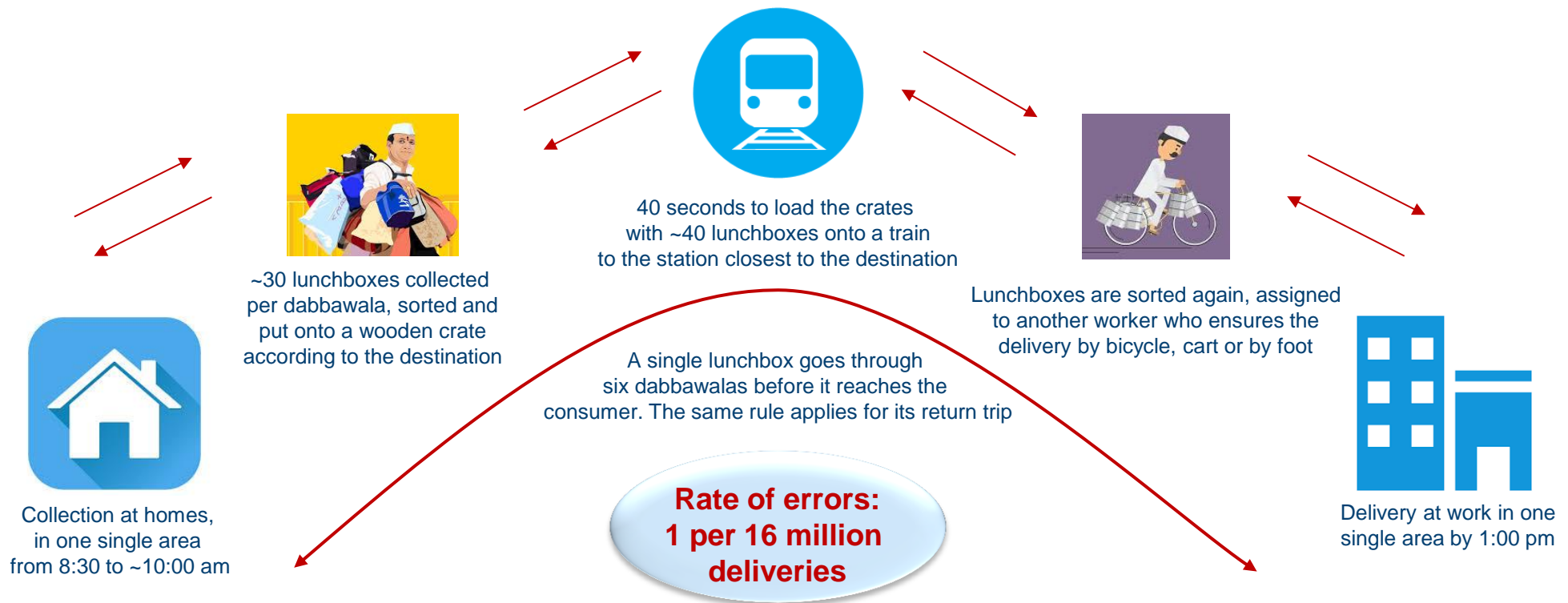
Sources: Sources: “How Dabbawalas became the world’s best food delivery system” by Emma Henderson, Independent (2017) – Smart Pharma Consulting analysis

¹ Which is considered as a good salary in India, especially for unskilled labour

6. Case Study: The Mumbai Dabbawalas

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

Description of the Business Model* (2/2)



6. Case Study: The Mumbai Dabbawalas

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

Analysis of the Business Model

Activities

- Each dabbawalla is responsible for his allocated group of customers
- Workers with more than 10-year experience serve as supervisors¹
- Tight schedule helps synchronize everyone and imposes discipline

Structure

- 200 units of 20-25 groups of dabbawalas are headed by a supervisor
- Flat structure ensuring agility
- 2 committees² tackle operational and organizational issues

Process

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

Culture

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

Dabbawalas mission: “Delivering food on time every time”

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

¹ There are 635 supervisors amongst the 5,000 dabbawalas – ² The Operational Committee and the Charitable Trust –

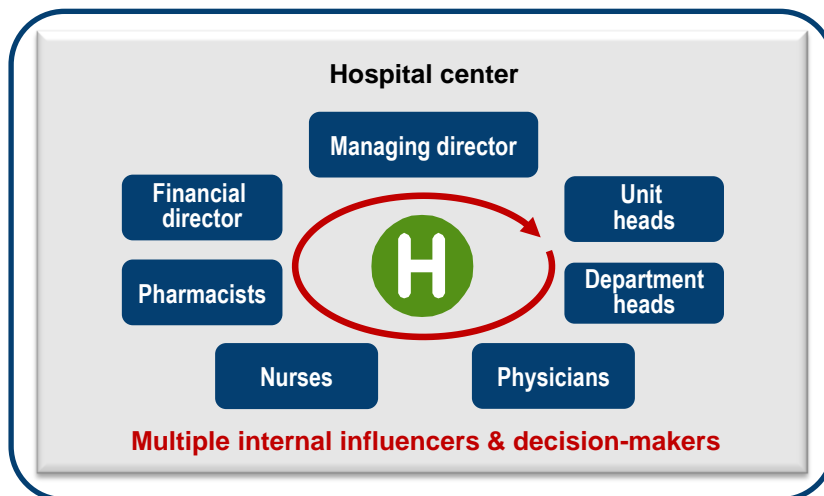
³ As shown by the coding system, the standardization of lunchboxes size and shape

7. Pharma Medico-Marketing & Sales Application

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

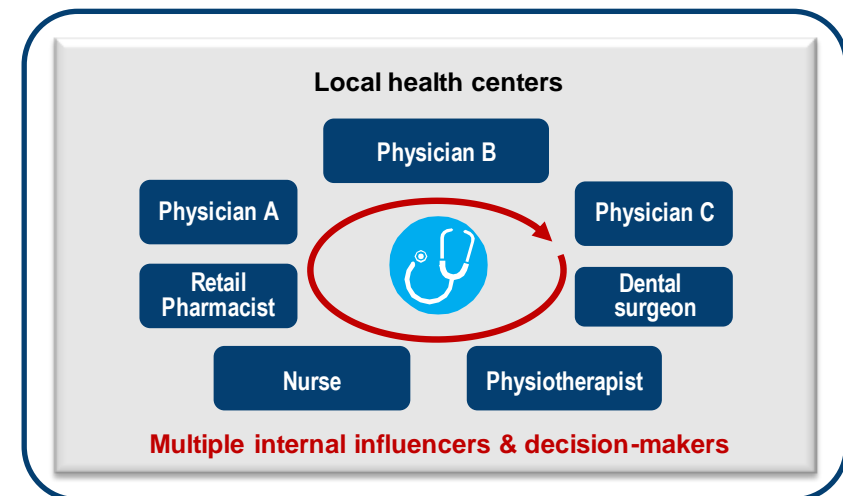
Situation analysis (1/2)

Hospital market segment



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

Open care market segment

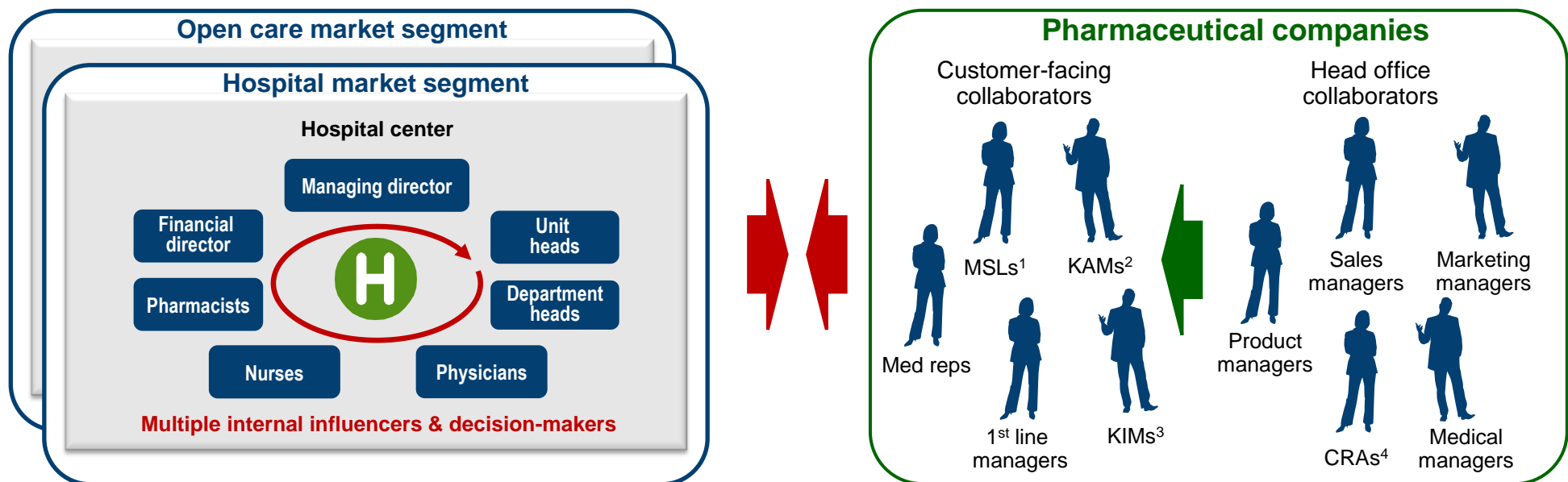


- Office-based physicians prescribing behavior is more and more under the influence of health authorities, payers or other HCPs
- Access to HCPs on the open care market segment has become a major issue for Field Forces

7. Pharma Medico-Marketing & Sales Application

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

Situation analysis (2/2)

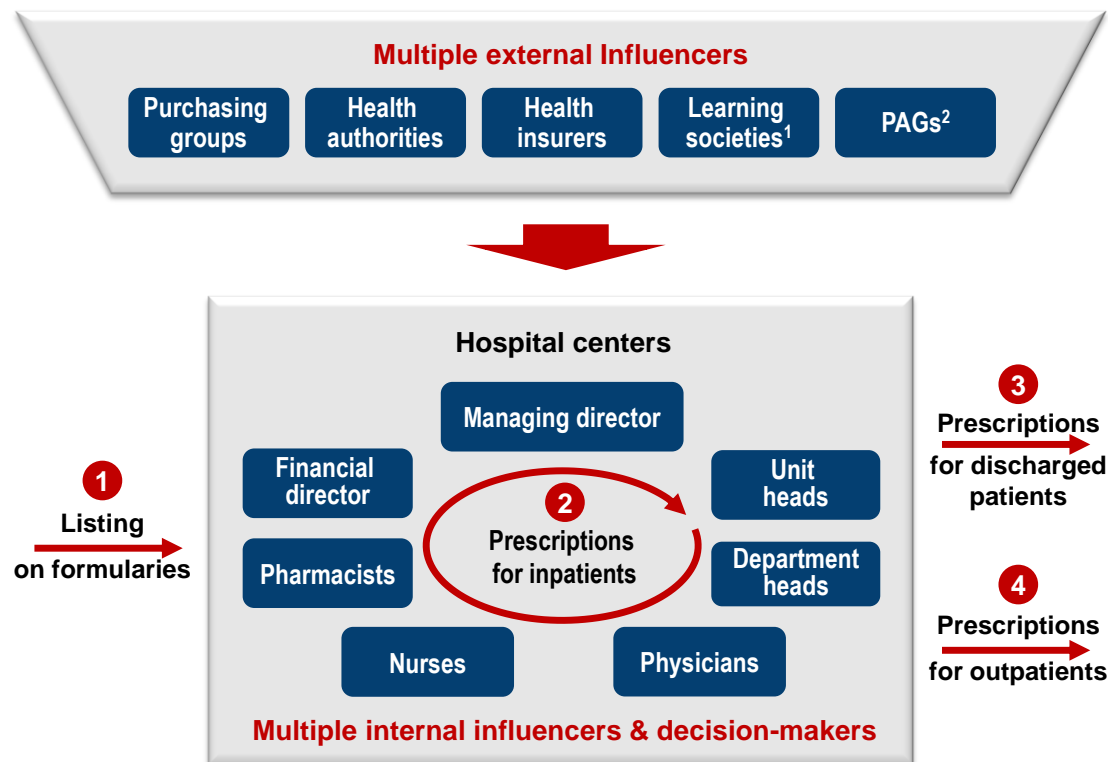


- Pharma companies have to address two key issues:
 - To protect, as much as possible, the price of their drugs
 - To move from a B-to-C to a B-to-B business model in which the prescribing decision is made by multiple stakeholders having different views and objectives

7. Pharma Medico-Marketing & Sales Application

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

Strategy Crafting on the Hospital Market



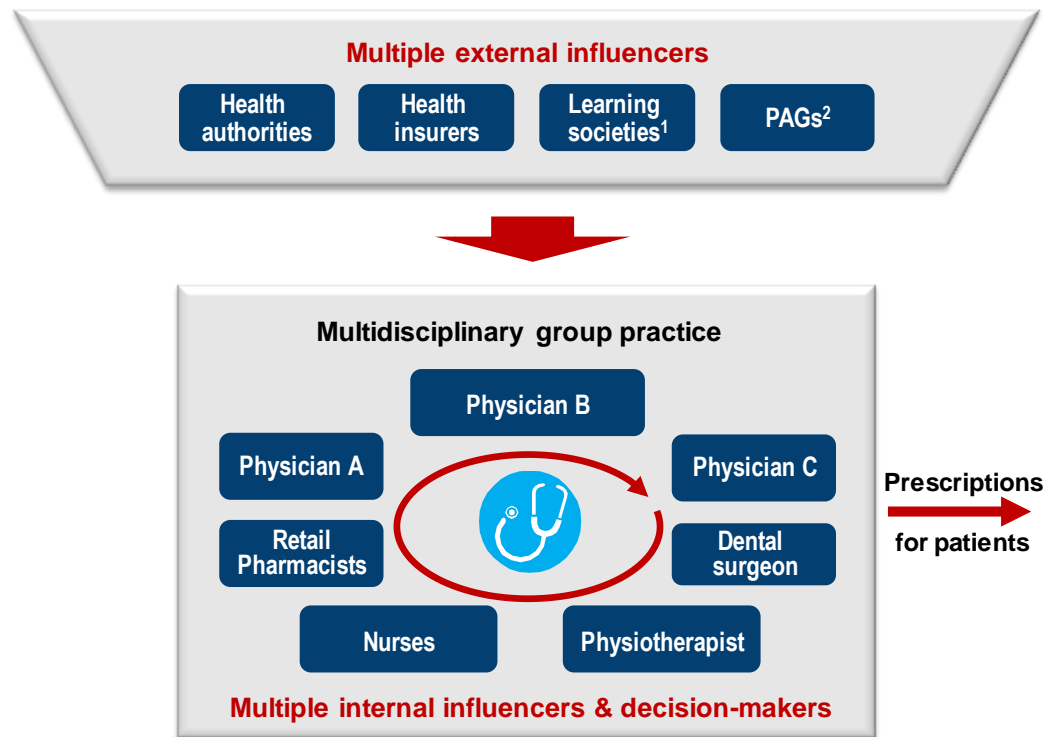
● Key performance drivers for pharma companies

- To boost their performance at hospital center level, pharma companies should activate one or several of the following key performance drivers:
 1. The listing on formularies³
 2. The prescription for inpatients⁴
 3. The prescription for discharged patients⁴
 4. The prescription for outpatients⁴
- 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

7. Pharma Medico-Marketing & Sales Application

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

Strategy Crafting on the Open care Market

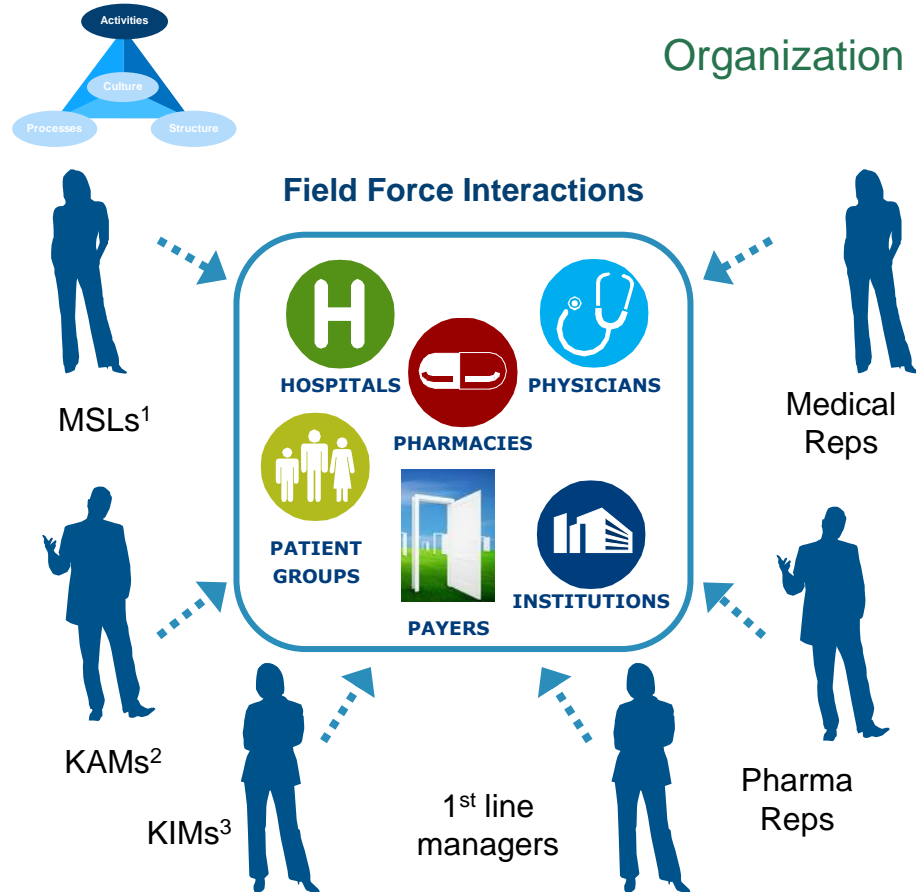


- The expected outcome from customer strategy on the open care market is to:
 - Secure regular access to HCPs which is particularly difficult in health centers
 - Raise HCPs preference in favor of marketed products by leveraging the three components of the Brand Preference Mix³
 - Maintain a favorable opinion and behavior of stakeholders who are likely to influence HCPs and patients
- To address these challenges, the Field Force Team members will have to:
 - Ensure highly valued interactions
 - Coordinate their activities to leverage potential synergies
 - Be flexible enough to adjust themselves to the external and internal changes

7. Pharma Medico-Marketing & Sales Application

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

Organization – Key activities (1/2)



- Activities of Field Force Teams should be systematically streamlined:
 - Activities having no significant impact to raise the value of the marketed brands should be stopped
 - Customers shared by different Field Force functions (e.g. MSLS and medical reps) require a clear co-positioning to avoid duplication and a thoughtful coordination of activities to leverage potential synergies which will be driven by sharing competencies and/or costs
- To secure access to customers and influence them, Field Force Teams should, better than competitors:
 - Acquire a high level of market insights⁴
 - Highlight the image⁵ of the company they work for
 - Propose and deliver highly valued services
 - Exhibit the benefits offered by the marketed brands
 - Use customer preferred communication channels
- Ambitious capability building programs would be required

7. Pharma Medico-Marketing & Sales Application

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



Organization – Key activities (2/2)

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

Smart index = Knowing x Understanding x Behaving

Knowing

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

Understanding

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

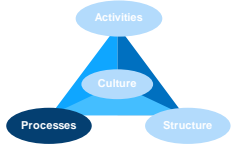
Behaving

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

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

7. Pharma Medico-Marketing & Sales Application

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



Organization – Processes (1/6)

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

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

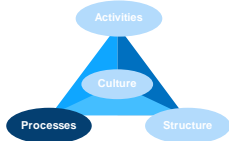


- Project teams including members from various departments centered around customers
- Shared customer database
- Introduction of metrics to foster cultural change

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

7. Pharma Medico-Marketing & Sales Application

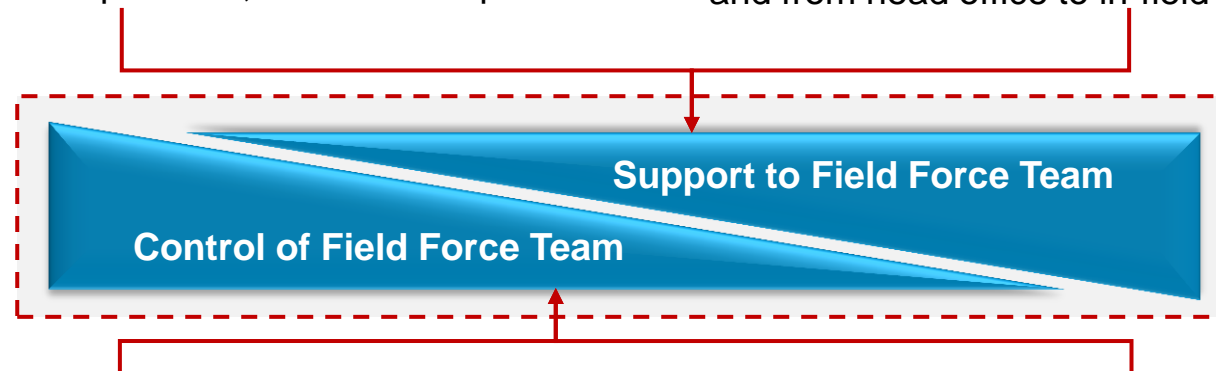
To create value for field forces, and therefore for the company, head office functions should maintain a business-driven balance between support and control



Organization – Processes (2/6)

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

- Support to facilitate in-field activities, to address scientific, legal, HR issues, etc.
- Competence and experience sharing across BUs and from head office to in-field functions



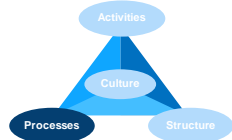
- Business-relevant metrics (automation, dashboards, standardized score cards)
- Selected number of KPIs (key performance indicators) and KEIs (key execution indicators)

- Monitoring of compliance (e.g. HR policy, people management, marketing & sales practices, etc.)
- Monitoring of the level of organizational agility and suggestions of solutions to fill up the gaps (if any)

7. Pharma Medico-Marketing & Sales Application

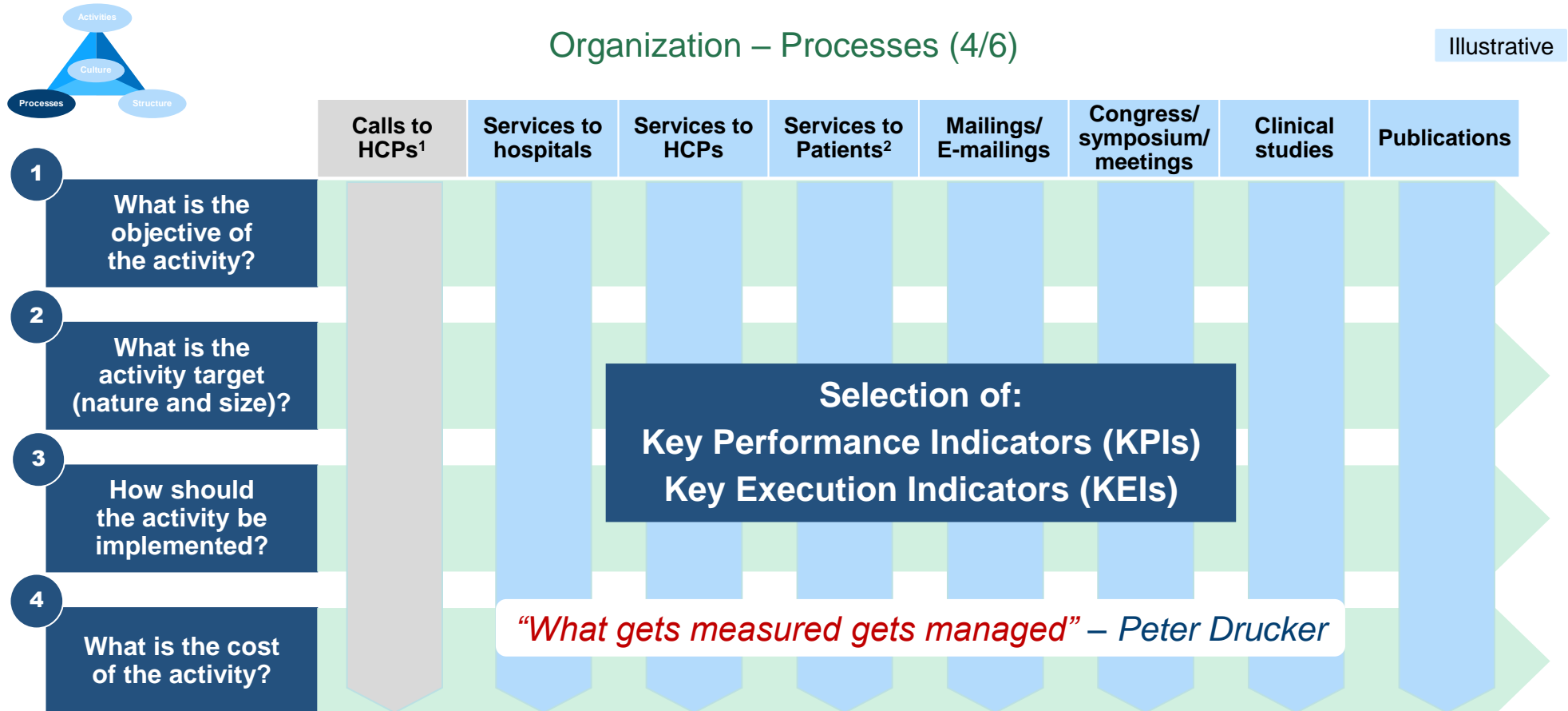
The activities of in-field collaborators interacting with the same customers should be integrated in a single strategic plan, including separated sections

Organization – Processes (3/6)



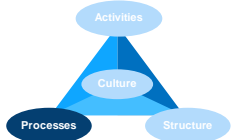
7. Pharma Medico-Marketing & Sales Application

Four questions would need to be answered before deciding to implement any activity, which should then be monitored with KPIs and KEIs



7. Pharma Medico-Marketing & Sales Application

Before making the decision to invest in medico-marketing or sales operations, the expected impact should be clearly defined, as well as execution and performance indicators



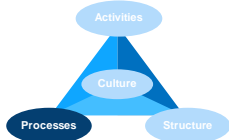
Organization – Processes (5/6)

Illustrative

What is the objective?	What is the target?	KEIs ¹	KPIs ²
<ul style="list-style-type: none"> Create / reinforce awareness Generate interest Develop brand preference Increase share of prescription Increase compliance Limit substitution rate Get the brand listed Fine tune the profile of the customer 	<ul style="list-style-type: none"> Physicians (e.g. KOLs, specialists, GPs) Pharmacists (e.g. retail or hospital) Patients Nurses Influencers (e.g. health authorities, “politics”, patient advocacy groups, public health insurance, private health insurance, professional associations) 	<ul style="list-style-type: none"> % of the target covered by the Field Force Team % of the target influenced by the Field Force Team % of the target having a positive opinion of the services offered Number of interactions (e.g. by customer, by in-field collaborator) Implementation time required vs. planned Actual vs. budgeted cost 	<ul style="list-style-type: none"> Brand Preference Mix index (i.e. corporate reputation, product attributes, service quality) % of hospitals having listed the brand Price negotiation Sales level and evolution Share of prescription Change in the number of treatment initiations Return on investment

7. Pharma Medico-Marketing & Sales Application

This type of tool is essential to prioritize and monitor the activities that are likely to contribute to reinforce the preference of customers for the brands



Organization – Processes (6/6)

Illustrative

Activity Description		Activity Objective		Target (HCPs, patients, etc.)			
Key steps					Perceived benefit by the target		
Description	Responsible	Timing	Cost (K€)	Comments	Evaluation*		Rationale
					Usefulness & Interest	1 2 3 4 5	
					Execution	1 2 3 4 5	
					Overall	1 2 3 4 5	

Barriers		Rationale	KPIs (Key performance indicators)	KEIs (Key execution indicators)	Expected Impact on Brand Preference Mix	
Technical	L – M – H	• Implementation	Indicate the metrics and the expected achievement	Indicate the metrics and the expected achievement	Brand	
Regulatory	L – M – H	• Compliance			Service	
Economic	L – M – H	• Estimated cost and return			Reputation	

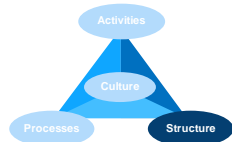
L: Low – M: Medium – H: High

* 1 & 2 below competitors – 3 as competitors – 4 & 5 above competitors

Source: Smart Pharma Consulting

7. Pharma Medico-Marketing & Sales Application

There is no magic numbers, the Field Force size depends on external and internal factors, the impacts of which are specific to each company and each product



Organization – Structure (1/2)

Illustrative

Field Force sizing: Driving Factors

External factors

Authorities

- Regulations re. Field Force activities (charter)
- Limitation of interactions with HCPs
- Refusal of institutions to interact with pharma companies

Customers

- Number of HCPs and other customers (e.g. influencers such as PAGs, patients, payers)
- Opinion and behavior vis-à-vis the company, its products and services
- Inclination of customers to change their opinion and behavior under the influence of Field Force Teams

Competition

- Number of targeted customers
- Type¹, content and frequency² of interactions
- Number of in-field FTEs

Key factors
to estimate
Field Force size

Internal factors

Products

- Number of brands
- Product life cycle stage (pre-launch, launch, growth, maturity, decline)

Organization

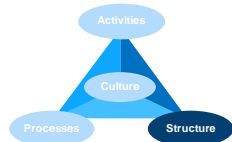
- Number of field days
- Type¹, content and frequency² of interactions
- Number of daily interactions
- Number of interactions per customers
- Cost per in-field collaborator and per interaction

Skills

- Quality of contact
- Contact productivity
- Territory management

7. Pharma Medico-Marketing & Sales Application

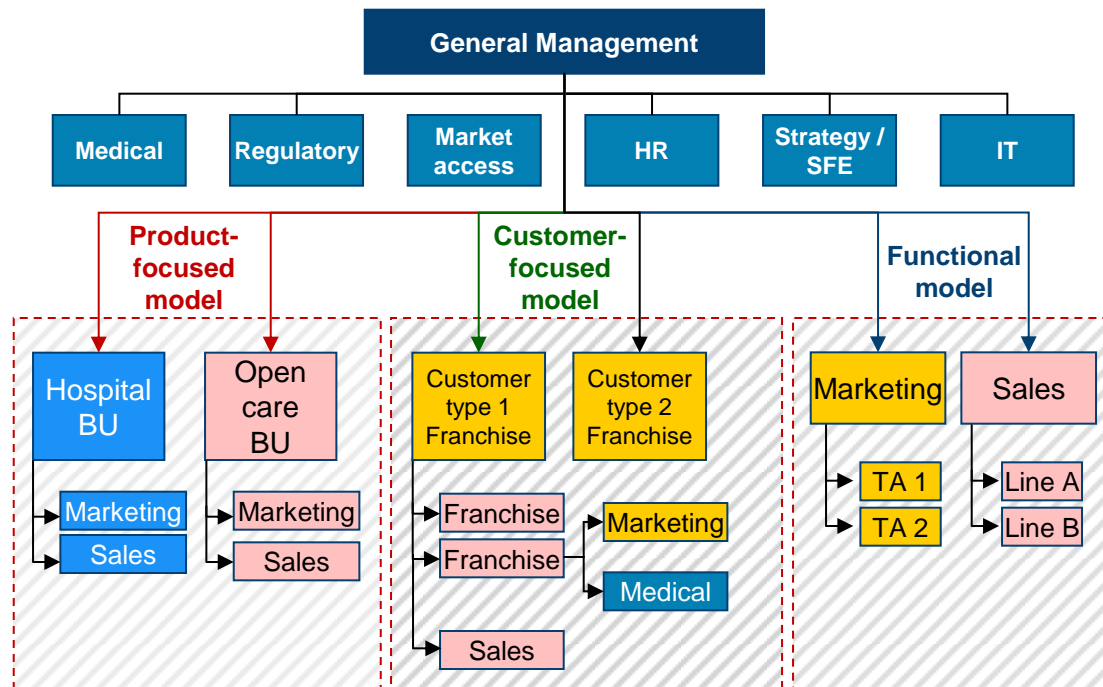
The preferred structure should be built around customers, remain lean and agile to favor collaborations across departments and with the support functions



Organization – Structure (2/2)

Illustrative

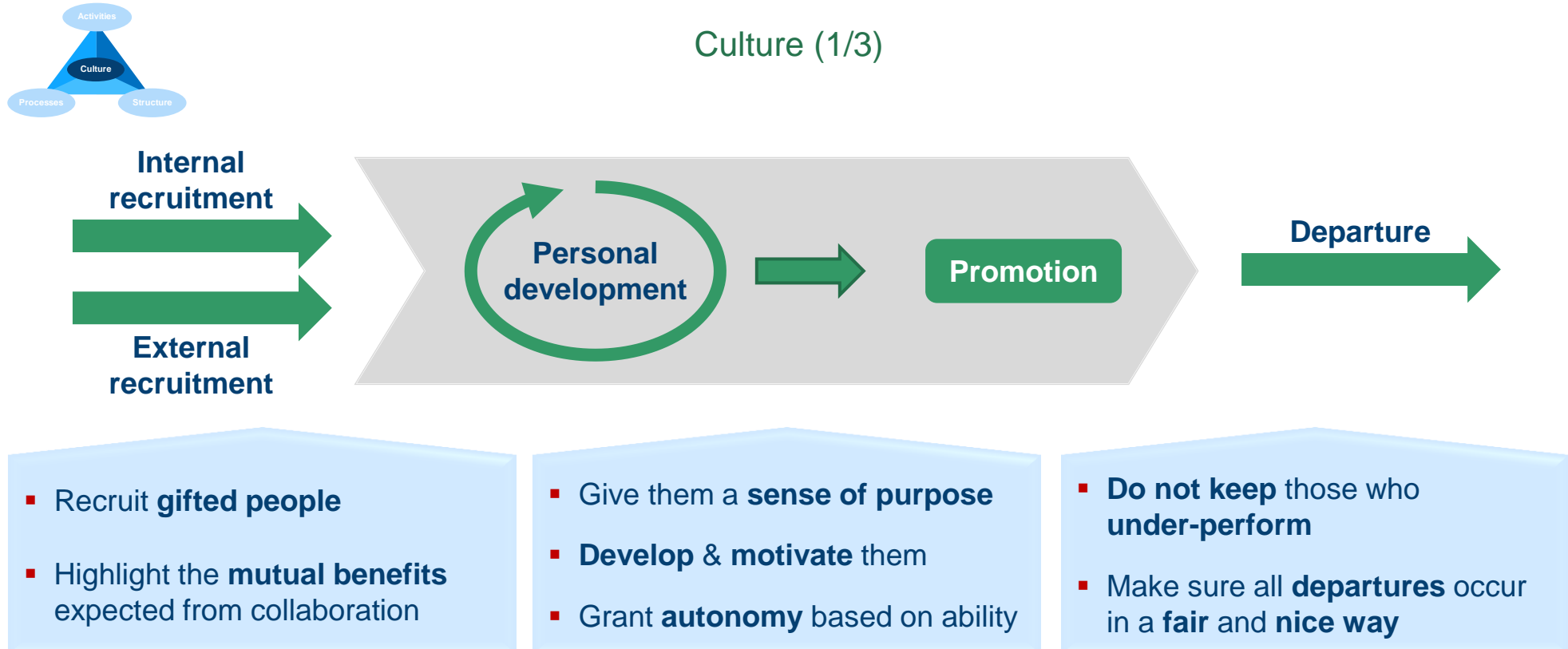
Typical structure of pharmaceutical companies



- In the **Product-focused model**, products drive the structure:
 - For “strict” hospital use, activities are organized in BUs or franchises, gathered or not under a common “Hospital Management” structure, and covering different therapeutic areas (TAs)
 - For mix products, companies display hospital dedicated med reps, reporting to open care BUs, and supporting detailing of open care products at hospital
 - Hospital and open care organizations are operationally independent, but share common supporting resources
- The **Customer-focused model** is shaped around customers by franchise, each of them containing marketing and medical resources, supported by sales forces
- The **Functional model** is less frequent among pharma companies, irrespective of their size

7. Pharma Medico-Marketing & Sales Application

Employees should be managed dynamically, by attracting best performers, developing and making them feel strongly engaged, while granting them the level of autonomy they deserve



“Alone we go faster, together we go further” – African proverb

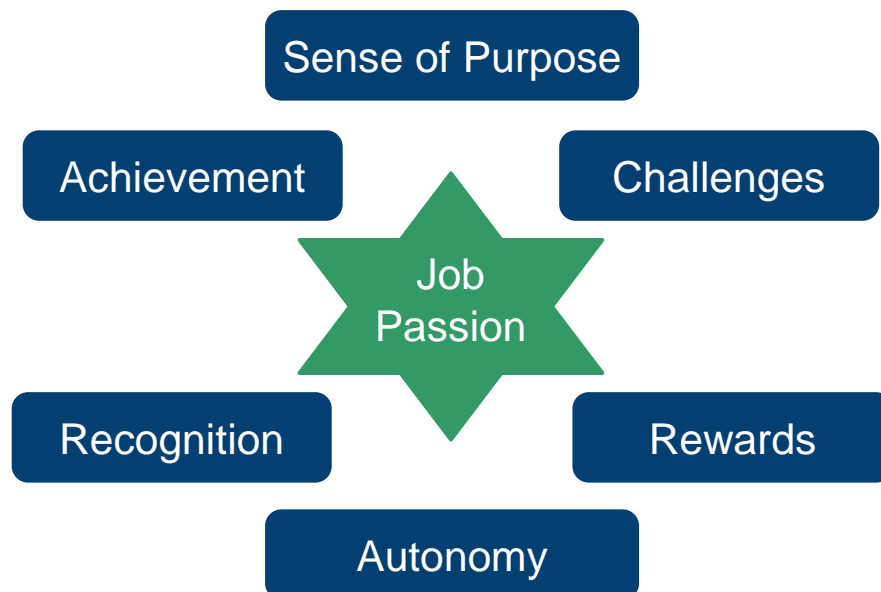
7. Pharma Medico-Marketing & Sales Application

Stimulating Field Force members passion for their job is a key performance driver, especially in a context where customers are increasingly reluctant to meet them



Culture (2/3)

Job passion is influenced by six key drivers



Passion is expressed by



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

7. Pharma Medico-Marketing & Sales Application

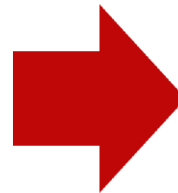
Managing by mutual benefits will give people a sense of purpose which will increase the probability to get their full and sustainable engagement



Culture (3/3)

MBO² (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**

8. Conclusion

Excellence in Execution requires to set a shared objective, the relevant strategy to reach it and high standards of quality, and to ignite the passion of collaborators

6 Tips to boost Excellence in Execution

- 1

 Set the **ambition** of delivering **product** and **service excellence** to customers, which are second to none
- 2

 The **strategy** set should be **explained** to align, inspire and **motivate** people in charge of its execution to excel
- 3

 The **structure** and **processes** should **facilitate / encourage** the search for **excellence** by all the collaborators of the company
- 4

 The **team** in charge of execution should be capable, accountable and **passionate** about exceeding customer expectations
- 5

 The executed activities should be **focused** on the **actions** the company excel at and that are the **most important** to support the strategy
- 6

 The **activities** supporting the strategy should be carefully **planed** and **monitored** with execution and performance indicators

“Excellence is a set of beliefs, ways of thinking, a matter of discipline, and ways of focusing”

8. Conclusion

If you have ticked seven “Yes” boxes or more, you are on the right track to move closer to Excellence in Execution, but keep in mind that excellence is a moving target

Where do you stand on the Excellence in Execution Scale?



		YES	NO
1	You have a clear understanding of the Purpose – Vision – Mission – Values of the company and you share it	<input type="checkbox"/>	<input type="checkbox"/>
2	The medical, marketing and sales objectives are achievable and the crafted strategy is appropriate	<input type="checkbox"/>	<input type="checkbox"/>
3	The organization is particularly well-designed to implement the strategy through your activities	<input type="checkbox"/>	<input type="checkbox"/>
4	You have the right means (human and financial resources) to implement the strategy	<input type="checkbox"/>	<input type="checkbox"/>
5	You have the right skills to meet customers expectations and raise their perceived value of your products	<input type="checkbox"/>	<input type="checkbox"/>
6	You know how to conduct projects in an effective and efficient way	<input type="checkbox"/>	<input type="checkbox"/>
7	You have built a good reputation with your customers	<input type="checkbox"/>	<input type="checkbox"/>
8	You are passionate about your job	<input type="checkbox"/>	<input type="checkbox"/>
9	You regularly measure the quality of execution and the impact of your actions	<input type="checkbox"/>	<input type="checkbox"/>
10	You feel highly satisfied and proud when you manage to excel in the execution of an activity	<input type="checkbox"/>	<input type="checkbox"/>

9. Training program – Intra-company

How to apply the principles of Excellence in Execution?

Content & Organization

- The program will include basic definitions, recommendations, key tools, practical exercises and case studies relative to the pharmaceutical industry
- The program content will be customized according to the specific needs of the clients
- The program duration will be of one day, one day and a half or two days, according to the client needs

Target Audience

- Any collaborators from pharmaceutical companies, whatever their level of responsibility and seniority
- Participants can be part of the medical, marketing, commercial, market research, strategic,... departments

Example of a One-Day Program

9:00	Introduction to the program
9:10	Review definitions and basic principles related to Excellence in Execution, in general and in the context of the pharma business
10:40	<i>Break</i>
11:00	Exercises: Setting strategic objectives – Crafting a strategy – Selecting and executing supporting activities – Designing the appropriate organization
12:30	<i>Lunch</i>
13:30	Case study #1: Practical implementation
15:00	<i>Break</i>
15:20	Case study #2: Practical implementation
16:50	Conclusion and key takeaways
17:30	End of the program

The Smart Manager *Series* (#5)

Storytelling in Business

**Key principles
&
Tools**

Survival Kit

June 2019



**Smart Pharma
Consulting**

*"The most powerful person
in the world is the storyteller"*

– Steve Jobs

1. Introduction

Storytelling is a unique tool to communicate a message,
it captures attention and engages the mind through emotions

- The purpose of business storytelling is to help improve credibility and engagement to an organization through the sharing of a well-constructed speech
- The aim of this position paper is to understand the power of storytelling as a tool in business and to provide the key practices to best implement it in organizations



*“We want to hear information through stories, with villains, characters, and a hero to rally around.
It’s the way the world and our brains work. We’re wired that way” – Carmine Gallo*

*“Marketing is no longer about the stuff that you make,
but about the stories you tell” – Seth Godin*

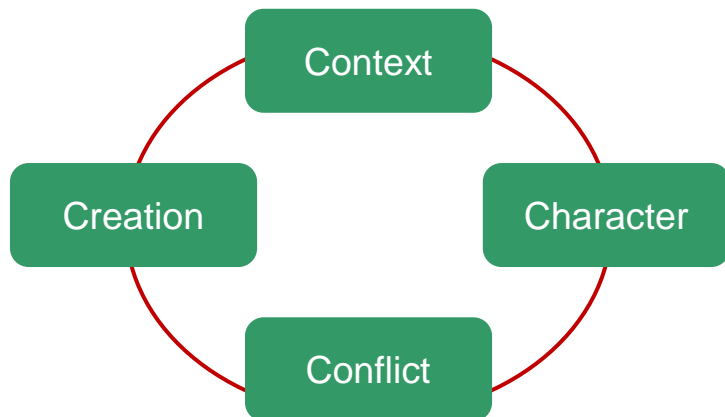
What is storytelling?

Storytelling is a very old technique which is considered as one of the most effective and influential means to reach people and move them with a message

Storytelling consists in sharing stories through different media to disclose the narrative of a story

- A story describes what happened
- A good story helps you see what happened
- A great story helps you feel what happened

The 4 Cs of a story



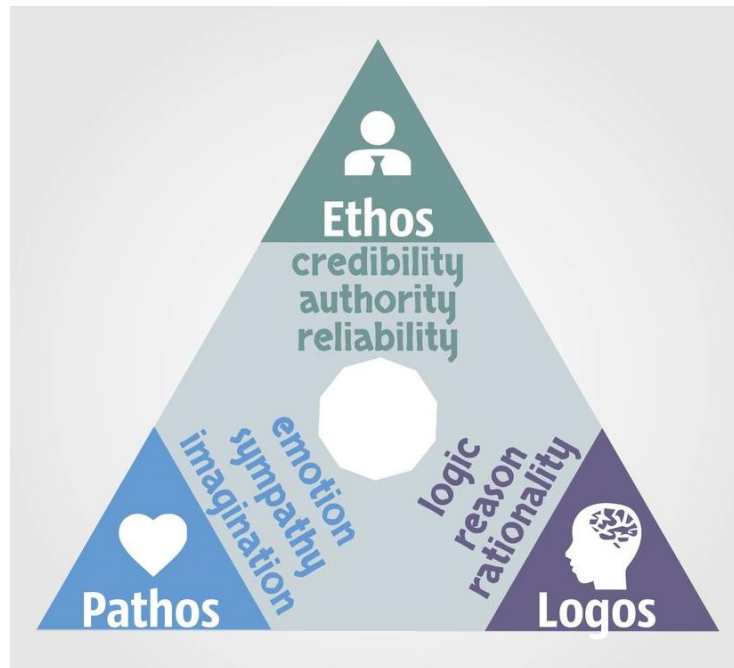
To create a great story, 4 components are required:

- The Context which indicates when and where the story happened
- The Characters to create connections and emotion with the audience
- The Conflict which drives the action of the story, creates tension and that is likely to be resolved at the end of the story
- The Creation which defines the telling, the way the context, characters and conflict are articulated into a narrative

“A story is a fact wrapped in context and delivered with emotion” – Indranil Chakraborty

Storytelling & modes of persuasion

The Aristotle's modes of persuasion, based on the ethos, logos and pathos triad build credibility, stir emotions and prompt action



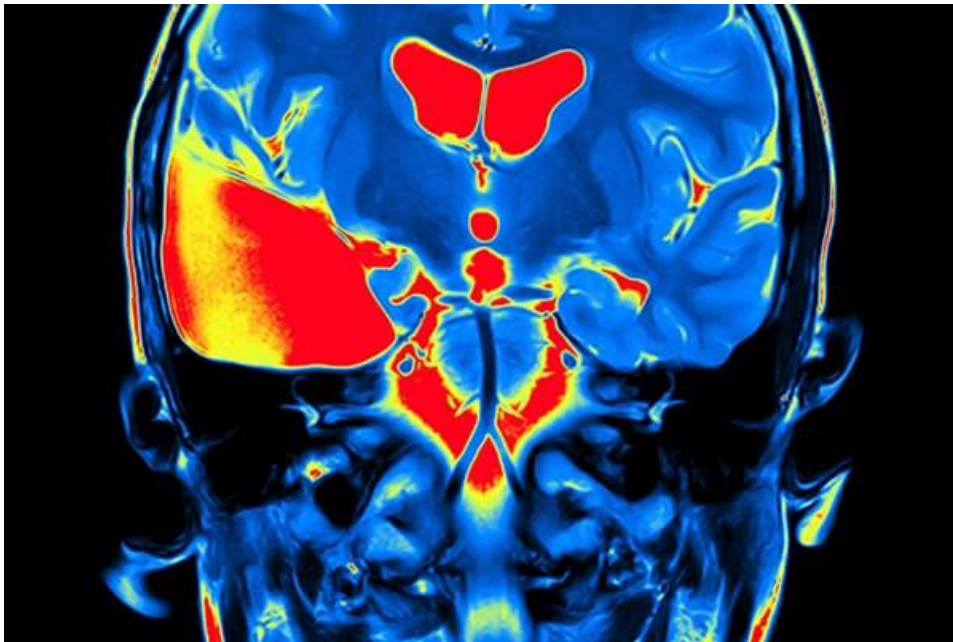
Aristotle has written “*The Art of Rhetoric*”, more than 2,000 years ago in which he proposed three modes of persuasion:

- **Ethos** (credibility) of the storyteller which depends on his:
 - Good sense Good moral character Goodwill
- **Pathos** (emotion) which is used to build a common bond with the audience through a shared identity and/or shared values, and inspire action by stirring emotions such as:
 - Anger and Calmness Friendship and Enmity
 - Fear and Confidence Shame and Shamelessness
 - Kindness and Unkindness Pity and Indignation
 - Envy and Emulation
- **Logos** (logical argument) is based on:
 - Deductive reasoning (e.g. syllogism¹)
 - Inductive reasoning (from specific to general²)

and is important to demonstrate strong evidence with the help of facts, figures and testimony to support conclusions

Storytelling & Neuroscience

Neurobiological findings on storytelling have shown that character-driven stories with emotional content are more persuasive and memorable



Storytelling evokes strong neurological responses:

- The stress hormone **cortisol** is produced by our brain during the tense moments in a story, which helps the audience to focus
- The **oxytocin** (the “feel-good” chemical) is produced when we are trusted or shown kindness, and it motivates cooperation with others
- A happy ending to a story triggers the limbic system – our brain’s reward center – to release **dopamine** which makes us feel more hopeful and optimistic
- Character-driven stories cause increased oxytocin synthesis which motivates people to engage in cooperative behaviors
- Studies have shown that, in order to motivate a desire to help others, a story must first sustain attention by developing tension during the narrative

Sources: “The irresistible power of storytelling as a strategic business tool”, Harrison Monarth in the Harvard Business Review (March 2014) – “Why your brain loves good storytelling”, Paul J. Zak in the Harvard Business Review (October 2014) – Smart Pharma Consulting

Why use storytelling? (1/2)

It has been shown that storytelling makes facts and figures delivered with emotion more convincing and memorable, and thus more persuasive

- Storytelling is deeply rooted in making an emotional connection with another person
- The neuroscientist Antonio Damasio has shown that emotions play a central role in decision-making
- The British Institute of Practitioners in Advertising (IPA), analyzed the impact of 1,400 marketing campaigns on profit gains and demonstrated that, when based on...:
 - ... logic, they are 16% effective
 - ... emotion, they are 31% effective
 - ... logic and emotion, they are 26% effective
- Stanford Marketing Professor Jennifer Aaker has shown that stories are remembered up to 22 times more than facts and figures alone
- Millennials¹ (or Generation Y) and Generation Z² base their relationships with brands on emotional attachments with stand-out companies
- People are more and more keen to give a sense to what they do
- Storytellers can engage audiences deeply with the right balance of emotion and key facts

Storytelling

- Captivates interest
- Remains in the memory
- Gets to the heart

“To win a man to your cause, you must first reach his heart” – Abraham Lincoln

Why use storytelling? (2/2)

Storytelling can be used to shape vision, to pass on knowledge and wisdom
and to shape identity and organizational culture

- A story **creates an emotional** experience that the audience will remember
- Some brands (e.g. Apple, Coca-Cola, Virgin, etc.) trigger an **emotional feeling** – positive or negative
- These brands, like many others, have a **personality**
- This personality, **generating emotions**, differentiates a brand from a product
- The critical aspect of stories is the feeling they create; so one must relate to **stories associated** to the **brands** and **not to its commercial elements**
- The **corporate narrative** provides the framework for getting **everyone on the same page**
- Stories can **help** — internal and external — audiences **understand the value** of a product, a company, a decision
- A clear narrative **helps** employees **appreciate the vision** of where the **company** is headed and **empowers** them **to use** their own **creativity** to **get there**
- Corporate story and storytelling **help leaders** to **communicate their vision** to their community
- A powerful way to **persuade** people is **by insinuating an idea with an emotion**
- A **compelling story** combines information and actions to **stimulate emotion** and **energy**

“90% of human behavior and decision-making is driven by our emotions” – Christine Comaford

Telling the right story: Seven narrative patterns

Telling the right story will provide meaning and evoke a sense of purpose while helping the audience relate, empathize and remember

To spark action



- Describe, straight to the point, how a successful change was implemented in a way the audience imagines how it might work for them

To tell who you are



- Tell who you are, what you have done, what you think, based on a life event that reveals some of your strengths or weaknesses from your past

To transmit values



- Use characters – real or fictional – in a situation that will prompt discussion about the issues related to the value being promoted

To foster collaboration



- Tell a story that collaborators have also experienced and that prompts them to share their own stories, and have a plan ready to tap the energy released

To communicate on brands



- The story should relate to products, services or companies and reflect the brand promise as it is delivered and perceived

To share knowledge



- Focus on mistakes made and show how they were corrected, with an explanation of the reasons why the solution worked, and solicit other solutions

To lead into the future



- Evoke the future you want to create without providing excessive details that will only turn out to be wrong

Business storytelling tips

The 5 following essential tips will guide the preparation and delivery of business storytelling likely to be successful

**1. Know
the audience**

**5. Involve
the audience**



**2. Define
the right message**

**4. Keep it
simple & visual**

3. Be authentic

1. Know the audience

The stories should be crafted according to the audience perspective,
and thus the same story should be adapted accordingly

- You must know your audience:
 - What are the audience experiences and expertise?
 - What are their thoughts and concerns?
 - What are their needs and wants?
 - What do they expect from you?
 - What would resonate well to them?
- Thus, to tell the right story, it is essential to know what the audience values and what the audience is likely to be interested by to create empathy and craft a story which is relatable



“Make sure you find common ground with people to whom you are telling stories” – Nancy Duarte

2. Define the right message

The message that will be conveyed should serve the objective of the storytelling and in a form that will generate emotion and empathy

- Define the **idea** you want to **communicate** according to your **intent** (e.g. the action you want the audience to take, the feeling you want them to have, the opinion you want them to modify)
- The **way** you will **communicate** your message should be **related** to the audience on a human level
- Do not just share information, ... tell a story:

Information sharing

“Smart Pharma has helped more than 80 companies addressing strategic, management and organizational issues”



Likely to be perceived as boring and not different from competition

Vs.



Storytelling

“Imagine your smartphone breaks down. Don’t worry because at Smart Pharma we deliver services 24/7 to solve your problems”



By using metaphors and anecdotes, it is possible to tell compelling stories

“People will forget what you said and did but will remember how you made them feel” – Maya Angelou

3. Be authentic

Authenticity is key to gaining audience trust and creates an emotional connection, without fear, to show your own challenges and failures

- Ideally, storytelling should not be fictional because a genuine narrative is more likely to connect with the audience
- If the audience can relate to a real-life story, you are making a connection and building trust
- Anecdotes that illustrate overcoming struggle, failures and barriers are what makes the teller appear authentic
- Storytelling is an effective way to communicate if you actually mean what you're saying
- The key is to show some vulnerability
- Be you, just you! Don't pretend to be anyone else
- If your stories are honest and transparent, you can win over your audience
- Storytelling brings more authenticity into business...
- ... which explains why blogs and social media recommendations are so relied on and impactful



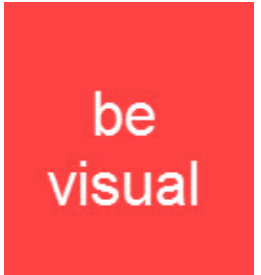
“The stories that move and captivate people are true to the teller and the audience” – Peter Guber

4. Keep it simple and visual

Most of the successful and memorable stories are relatively simple, straightforward and can be enhanced by a limited number of well-chosen visuals



- Apply the KISS principle: "Keep It Simple, Stupid"
- Messages should be clear, precise and concise, without focusing on the details
- Visual storytelling (e.g. animated images, videos) allows complex data to be broken down into smaller digestible pieces and chunks of memorable information
- Visual aids help improve engagement and retention
- Visuals are the most effective communication vehicles for evoking emotion and getting people to take action
- Simplicity is a challenge when subjects are complex
- The number of substantive arguments and persuasion principles should be limited



- Visuals drive emotions
- Emotions drive decisions
- Decisions lead to action

5. Involve the audience

Stories must be built and delivered so that the audience can feel involved as being a character of the story

- We cannot tell a story if we don't feel that there is someone listening to us and paying attention
- Storytelling is about connecting
- You need to be vulnerable and connect to the vulnerability of others
- We can't really listen to a story when the storyteller is not aware of his or her audience and is instead caught up in his or her own speech bubble
- In this most basic sense, there is a reciprocal relationship between listening and telling
- People like to be a part of stories
- Your audience can be characters in your stories
- Come up with ways to get your audience involved
- Get your audience involved in the presentation:
 - Ask questions
 - Brainstorm
 - Challenge them

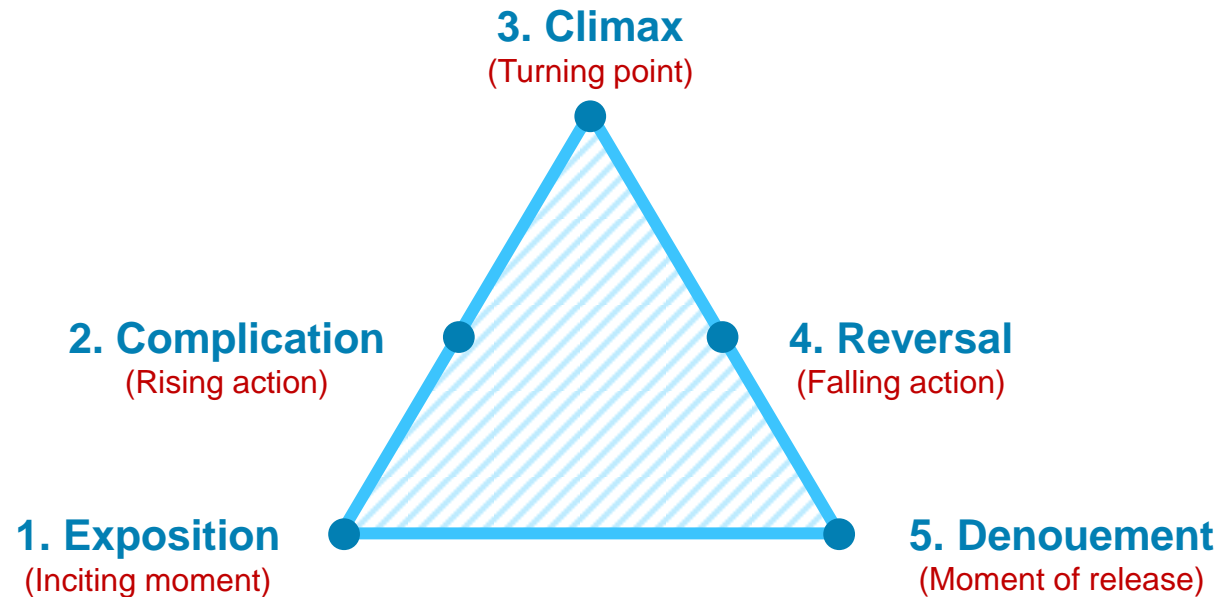


“A good storyteller makes the target audience part of the story he tells”

Structuring the story – Freitag’s Pyramid (1/2)

Freitag’s pyramid¹ uses a 5-part system to describe the story plot², the climax being the high point which is surrounded by rising and falling actions

To capture attention, convey emotion and engage the audience, stories need a dramatic arc, some conflicts to arise and after the struggle, a resolution



“A story without a challenge, simply isn’t interesting” – Caroline O’Hara

Sources: “The irresistible power of storytelling as a strategic business tool”, Harrison Monarth in the Harvard Business Review (March 2014) – Smart Pharma Consulting

¹ Gustav Freytag was a 19th century German novelist who saw common patterns in the plots of stories and novels and developed a diagram to analyze them – ² Sequence of events through the principle of cause and effect

Structuring the story – Freitag’s Pyramid (2/2)

Structuring stories by using Freitag’s Pyramid will help to raise audience attention and forge an emotional connection likely to change their opinion and behavior

3. Climax

- It is the most intense moment (either mentally or in action) or the greatest tension in the story, turning positively for the protagonist in a comedy or negatively in a tragedy

- A single event usually signals the beginning of the main conflict, rising tension
- The story builds as sequential events happen and...
- ... becomes more exciting with a series of conflicts and crisis

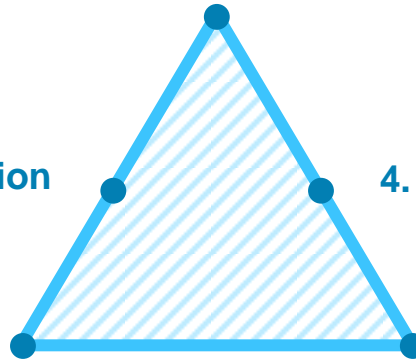
2. Complication

4. Reversal

- It is the event that occurs as a result of the climax, and marks up the story will end soon

1. Exposition

- This 1st step marks the start of the story where the scene is set (time and place)
- The teller introduces the characters¹ providing description of the situation and establishing the atmosphere of the story



5. Denouement

- At this point, any secrets, questions or mysteries which remain after the resolution are solved by the characters or explained by the teller

Note: As an example of the implementation of the Freitag's Pyramid, see the TED show presentation of Richard Tuere:
https://www.ted.com/talks/richard_tuere_a_peace_treaty_with_the_lions/up-next?language=fr

How to compose a story: Practical recommendations

To grab attention of the audience and make a story relatable, engaging and compelling, the story should be structured according to the classic narrative arc¹

- Know your audience to craft a story that has a meaning for them

I. Who is my audience?

- Why are you telling the story?
- What do you want the audience to think, feel or do at the end of the story?

II. What is the message I want to share?

IV. How I structure my story?

- Pick a main character similar to the audience
- Start your story with some context²
- Something must be at stake
- Have a happy or constructive ending from which lessons can be learned

III. What is the story I want to tell?

- Tell a story that has a meaning for you
- Tell a story that actually happened
- Pick a story that addresses a problem the audience has

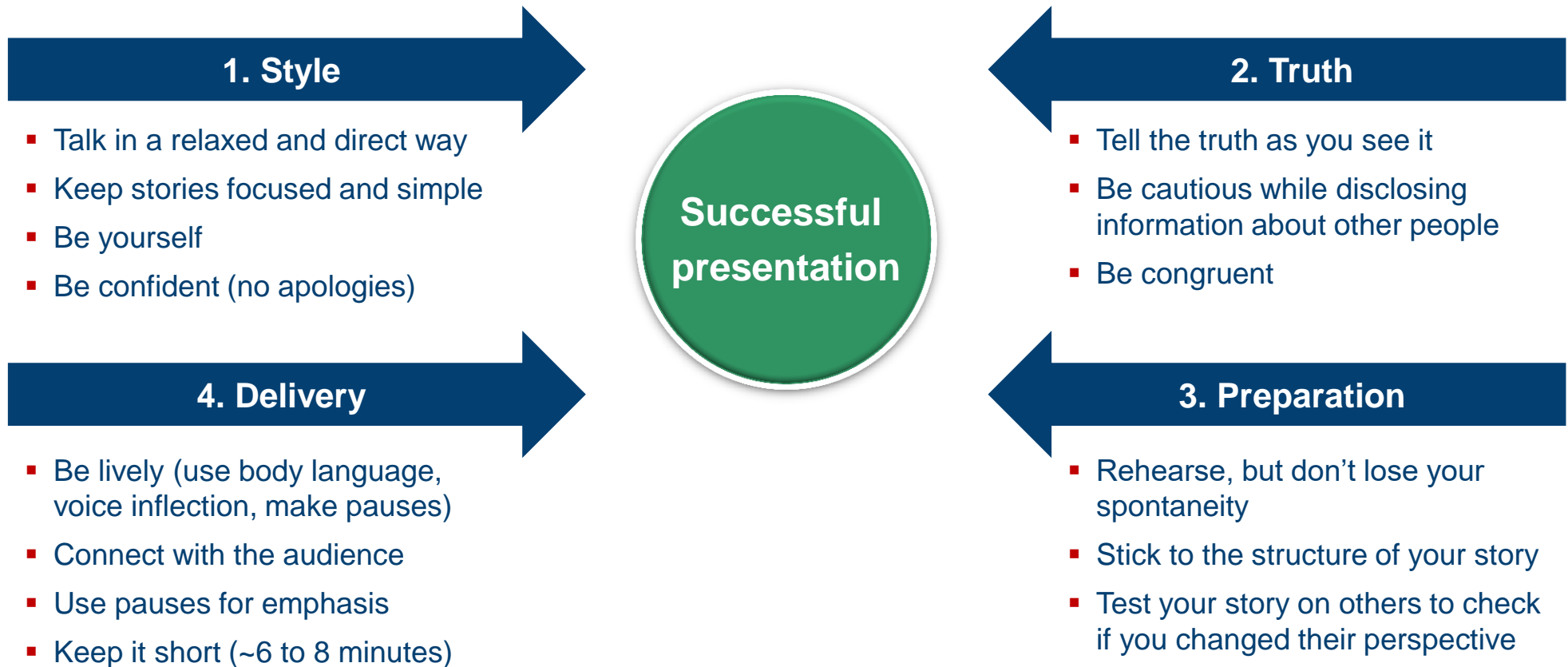
Successful composition

Sources: : "Storytelling and other strategies in the art of persuasion", Bill Chiat – Jennifer Aaker – Smart Pharma Consulting

¹ As per the Freytag's pyramid – ² Place, date, etc.

How to deliver a story: Practical recommendations

The delivery of the story being as important as its composition,
it is essential for the storyteller to be well-prepared and to practice



The Apple case

Steve Jobs was not a natural speaker but used to work really hard, rehearsing again and again to make keynote presentations look effortless and conversational

- Steve Jobs introduction of the first iPhone in 2007 was a masterpiece
- Steve Jobs begins the presentation by building suspense. A touchscreen iPod? A phone? An internet communicator?
- Then, even as the audience is starting to catch on, he lingers in the suspense a bit longer before making the reveal: a three-in-one mobile phone that would change the world forever
- Jobs was building the iPhone brand even before the audience had seen it, and the story was consistent with the company brand Apple had already built
- Apple knew they had made something exceptional
- Today, Apple continues Steve Jobs tradition of storytelling
- They do a great job of telling a story about what it looks like for customers to successfully use their products
- Apple weaves their products seamlessly into the story
- They also show how their products help people create their own stories, and Apple highlights the stories people create



What can we **learn from Apple?**

1. **Hook the audience** first, introduce your product second
2. **Build suspense**
3. **Focus your story on customers** successfully using your product

The Airbnb case

Airbnb has built its brand with storytelling marketing, focusing on people, telling stories about people, Airbnb hosts from around the world, thus creating connection

- Airbnb content is focused on the people who own the homes listed and the travellers who go there
- They show how connecting with others is important to their brand and how their brand makes that possible
- It is a very human approach with a clear statement about the importance of stories to the Airbnb brand
- There is an entire page on their website labelled airbnb.com/stories with videos and biographies of hosts around the world
- Airbnb is also experimenting, on their website, a brand magazine called Pineapple which is “a platform for incredible stories from Airbnb family to be shared; showing how people live and create connections in cities today”
- This meshes perfectly with Airbnb approach which focuses on stories and people, which is the language by which humans communicate; this approach attracting more customers



What can we learn from Airbnb?

1. **Always seek connection** between the brand and the audience
2. **Always bring it back to the human element**
3. **Be sincere**

Key learnings

Storytelling can help companies connect with their audience and build a long-lasting relationship of loyalty with their customers and increase employee motivation

- As an **emotional tool**, storytelling **creates purpose** and **drives action** from the audience
- Well-constructed storytelling is an effective tool to **inspire**, **engage** and **motivate** your team
- Through imagination, stories **help customers visualize** the **context** of a **company**, its **challenges** and **comprehend its strategy**
- Many **companies use** storytelling to tell their story, **share** their **values** and **aspirations** and **create** a **lasting bond** with their target audience
- In order to **craft an impactful story** to tell, an **analysis** of the targeted **audience** is required to **understand** its **concerns**, **perceptions**, **personalities** and **priorities**
- A **great crafted story** is **not sufficient** to move an audience, **its delivery** through a **plotted speech** is **necessary** to achieve a behavioral change
- Telling a great **story** can **help to leverage** the full **potential** of a **brand** and to distinguish from competition

“Stories evoke emotion and inspire action”

6. Training program – Intra-company

One-day program to define relevant storytelling

Content & Organization

- The program will include basic definitions, recommendations, key tools, practical exercises and case studies related to the pharmaceutical industry
- The program content will be customized according to the specific needs of the client
- The program duration will be of one day, one day and a half or two days, according to the client needs and desire

Target Audience

- Any collaborators from pharmaceutical companies, whatever their level of responsibility and seniority
- Participants can be part of the medical, marketing, commercial, market research, strategic,... departments

Example of a One-Day Program

9:00	Introduction to the program
9:10	Review definitions and basic principles related to storytelling, in general and in the context of the pharma business
10:40	<i>Break</i>
11:00	Exercises: Know your audience – Define the right message – Be authentic – Keep it simple & visual – Involve the audience
12:30	<i>Lunch</i>
13:30	Case study #1: Practical implementation
15:00	<i>Break</i>
15:20	Case study #2: Practical implementation
16:50	Conclusion and key takeaways
17:30	End of the program

*“Storytelling is the most effective way to
combine meaning & emotions”*

The Smart Pharma Publications

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

Smart Pharma 2019

Half-Year Publications

- This e-book is the collection of our publications from January to June 2019
- Thus, we have published seven new position papers:

Market Insight & Strategy

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

Management

- Hospital & Institution Relationships in Regions
- Strategic KOL Engagement Planning
- Excellence in Execution
- Storytelling in Business

Smart Pharma Consulting Editions



- Besides our consulting activities which take 85% of our time, we are engaged in sharing our knowledge and thoughts through our:
 - Publication of articles, booklets, books and business reports
 - Teaching and training activities
- Smart Pharma Consulting has published;
 - 17 business reports regarding:
 - The French healthcare system and pharma market
 - The French generics and biosimilar markets
 - The French pharma distribution
 - The French OTC market
 - The market access and drug valuation
 - The global biosimilars drugs market
 - The best performing pharma companies
 - The pharma digital marketing
 - 42 articles dedicated to pharma business issues
 - 66 position papers since 2012

Best regards,

Jean-Michel Peny