

20th Anniversary



Serving & Sharing with Passion

Strategy & Market Access

COLLECTION 2021

Top 20 Pharma Companies

Pharma Strategy Crafting

Pharma Strategy at Affiliate Level

Best-in-class Pharma BD&L

Patient-centric Strategy

How to boost Corporate Reputation

How can Creativity boost Performance

Drug Value & Access Optimization

PART 2

October 2021

1, rue Houdart de Lamotte – 75015 Paris – France
Tel. +33 6 11 96 33 78

Email : jmpeny@smart-pharma.com – Website : www.smart-pharma.com

This e-book is the Part 2 of the 20th anniversary collection of Smart Pharma Consulting's best position papers published, in line with its commitment to share knowledge and thoughts

Presentation of the 2016 – 2021 Publications

- On the 20th anniversary of Smart Pharma Consulting, we have compiled 34 position papers published since 2016
 - These publications propose effective and practical solutions to help pharma companies improve their performance
 - For so doing, we share openly:
 - Business insights
 - Concepts
 - Methods
 - Tools
- The majority of which have been developed by Smart Pharma Consulting
- This “2021 Collection” will be released in six parts:
 1. Market Insights
 2. Strategy & Market Access
 3. Medical Affairs & Marketing
 4. Sales Force Effectiveness
 5. Management
 6. Training Programs
 - We hope that this 20th anniversary “gift” will be of high value to you
 - We will keep on sharing with you our thoughts and recommendations in the years to come

Jean-Michel Peny

2. Strategy & Market Access



Top 20 Pharma Companies

MARKET INSIGHTS

Performance & Strategies

**This document proposes a review of global pharma trends by 2025
and an analysis of top 20 pharma companies' performance and strategies**

Introduction

Smart Pharma Consulting proposes to address the following issues:



What is the structure of the global pharma market and how should it evolve by 2025?



What has been the recent performance of the top 20 pharma companies worldwide?



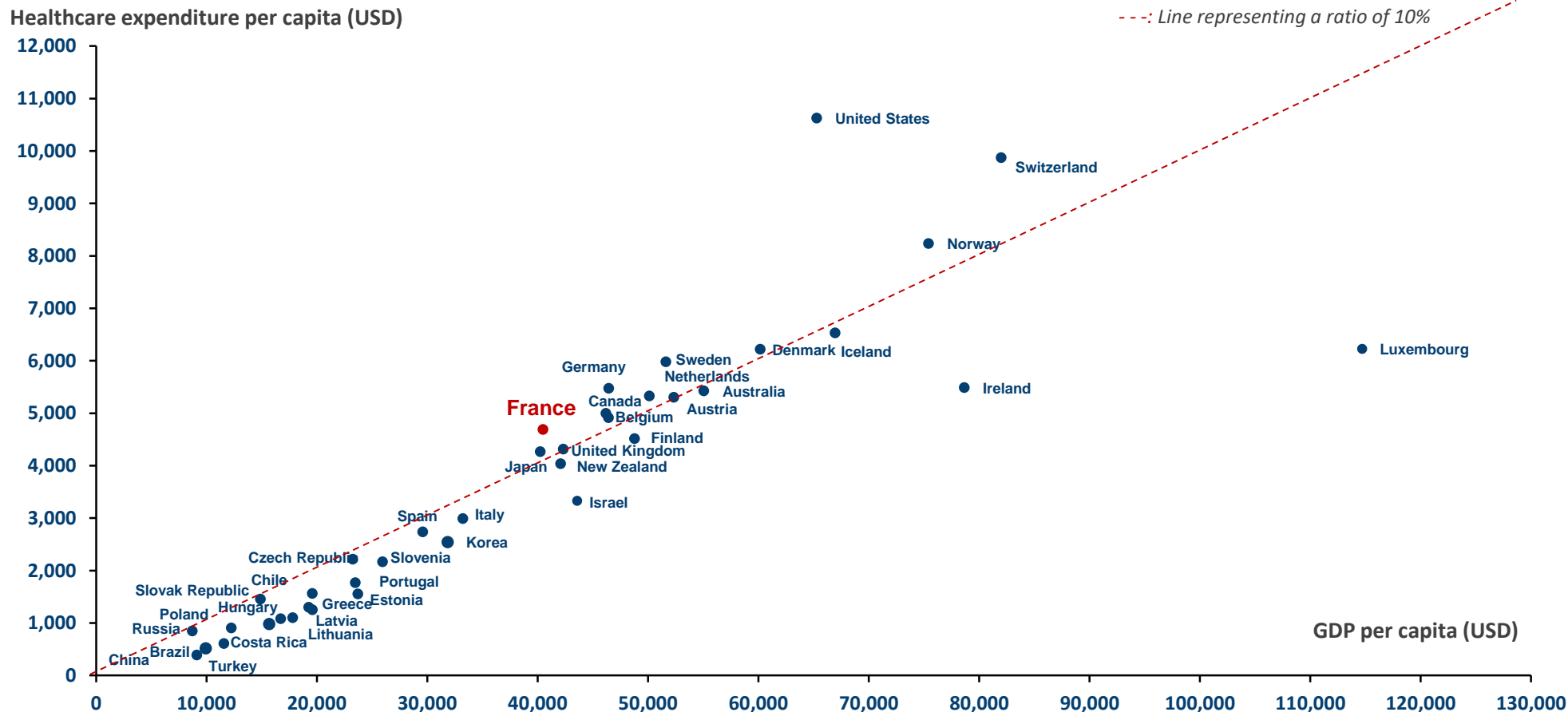
What are the current portfolio strategies of the top 20 pharma companies worldwide?



What have been the objectives pursued by the top 20 pharma companies in their recent M&A deals?

Healthcare expenditure and GDP¹ per capita are highly related and the ranking² of France (#15 and #19 respectively) shows that healthcare is a key national priority

Relation between GDP and healthcare expenditure per capita (2018*)



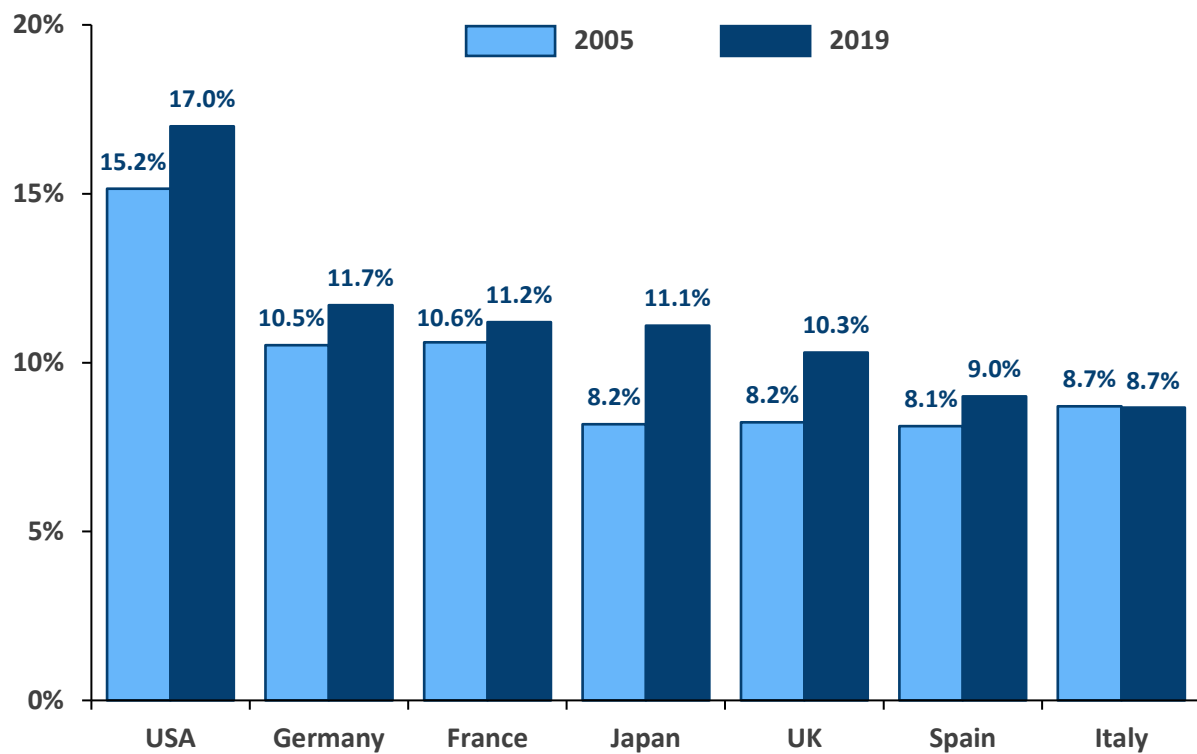
Sources: World Bank database (March 2021) –
 Smart Pharma Consulting analyses

¹ Gross Domestic Product – ² Amongst 44 countries in the world –
 * Or latest data available for all countries

Healthcare expenditure should 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 (2019*)

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

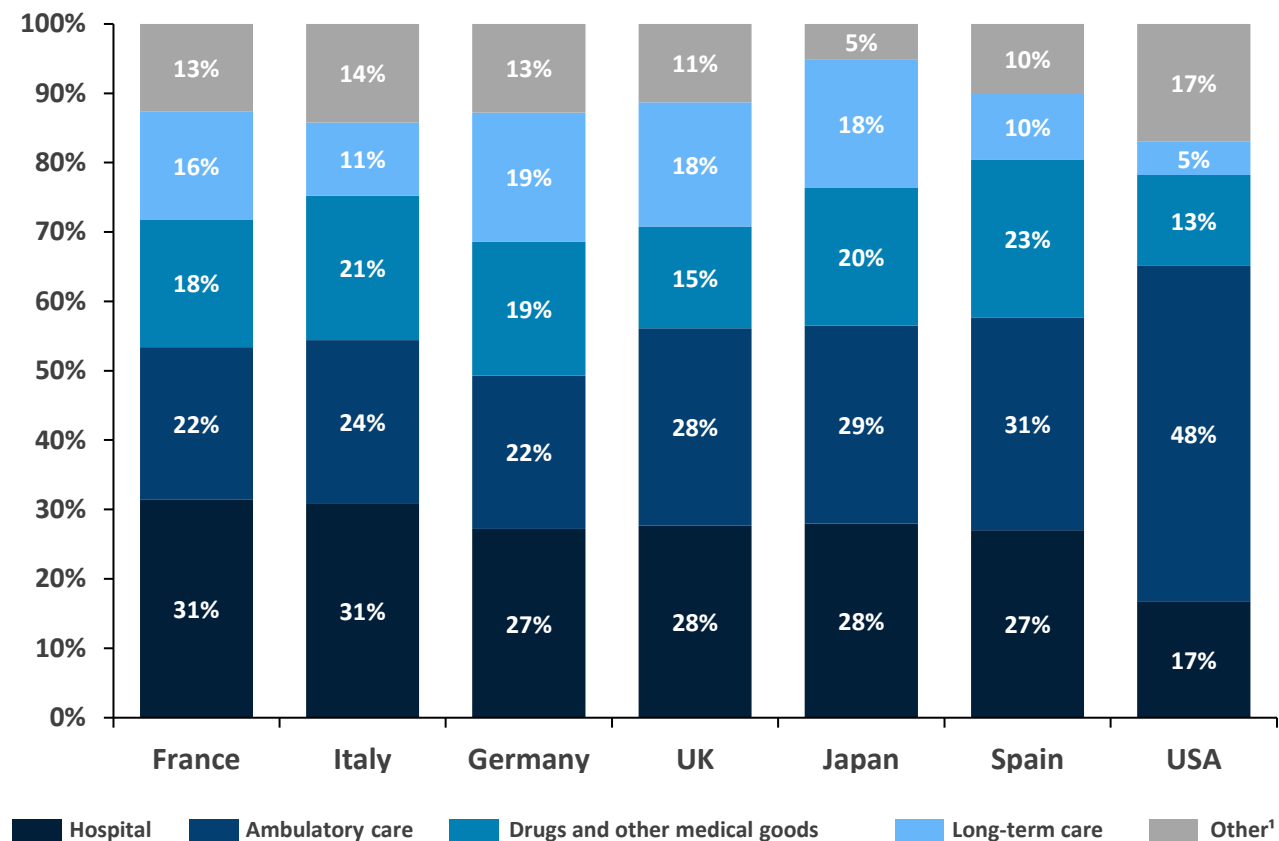


- Healthcare expenditure represents one of the largest public spending items in most developed economies: 1st (USA), 2nd (France, Germany, Japan and UK)¹ and 3rd (Italy and Spain)²
- At best, governments and payers will manage to slow down the rise of healthcare expenditure as a percentage of GDP but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

The cost of drugs is far behind that of hospital and ambulatory care, yet this segment is targeted by governments because it is technically and politically easier to control

Breakdown of healthcare expenditure per country (2019*)

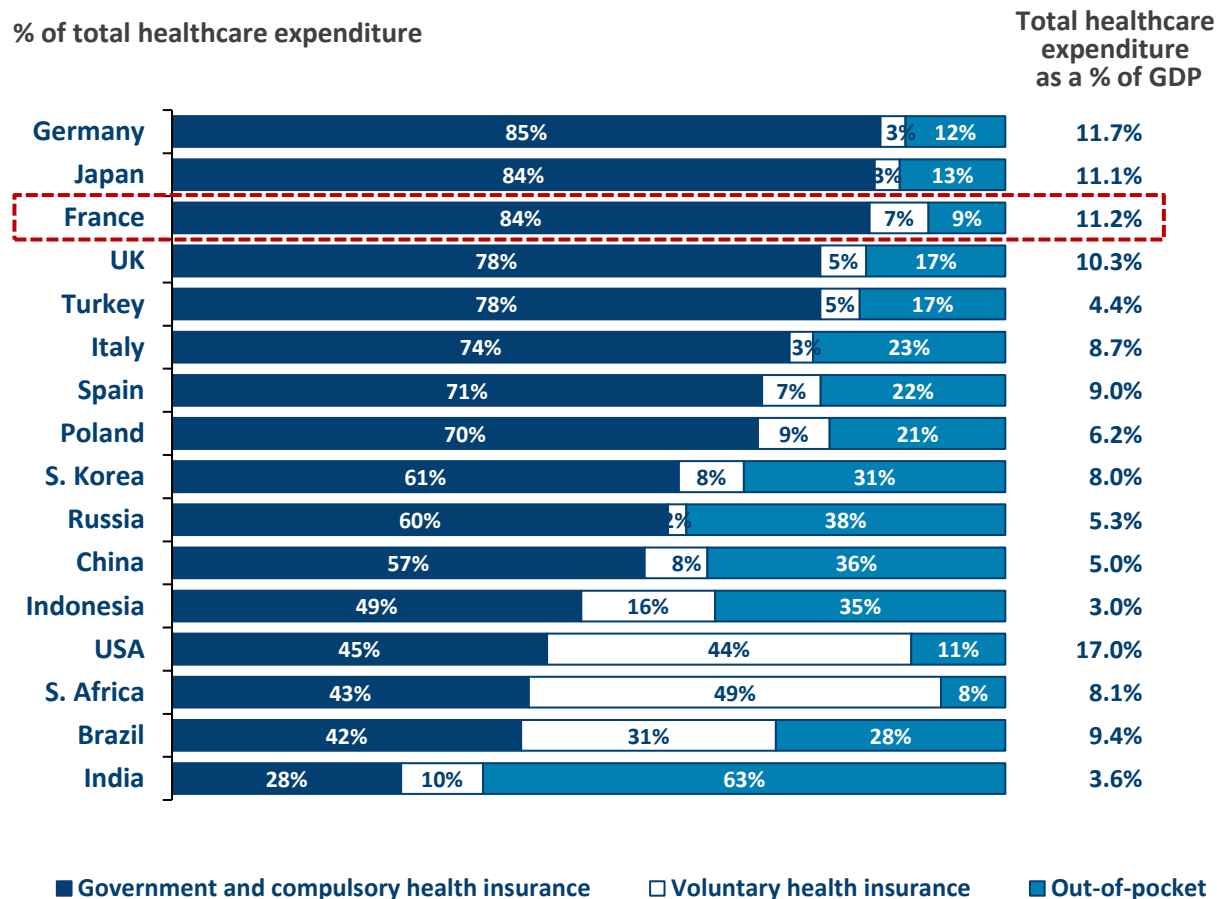
% of total healthcare expenditure



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

France is one of the countries where the percentage of “out-of-pocket” spending to cover the healthcare expenditure is the lowest

Share of public spending in total healthcare expenditure (2019*)



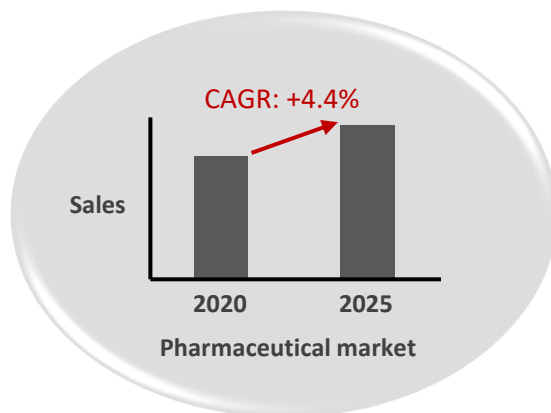
- With 11.2% of its GDP spent in healthcare, France belongs to the countries allocating the largest share of their resources
- Its level of public spending on healthcare is amongst the highest, just behind Germany and Japan, showing a highly protective healthcare system
- All the French citizens benefit from a public health insurance and 95% of them have a complementary private healthcare insurance, which is compulsory, since the 1st of January 2016, for all employees, irrespective of the size of their company
- As a result, “out-of-pocket” spending represents only 9% of total healthcare expenditure

The key drivers and limiters of the global pharmaceutical market by the end of 2025, as well as their probable impact on sales trends, are well identified and should remain stable

Global pharmaceutical market drivers and limiters (2020 – 2025)



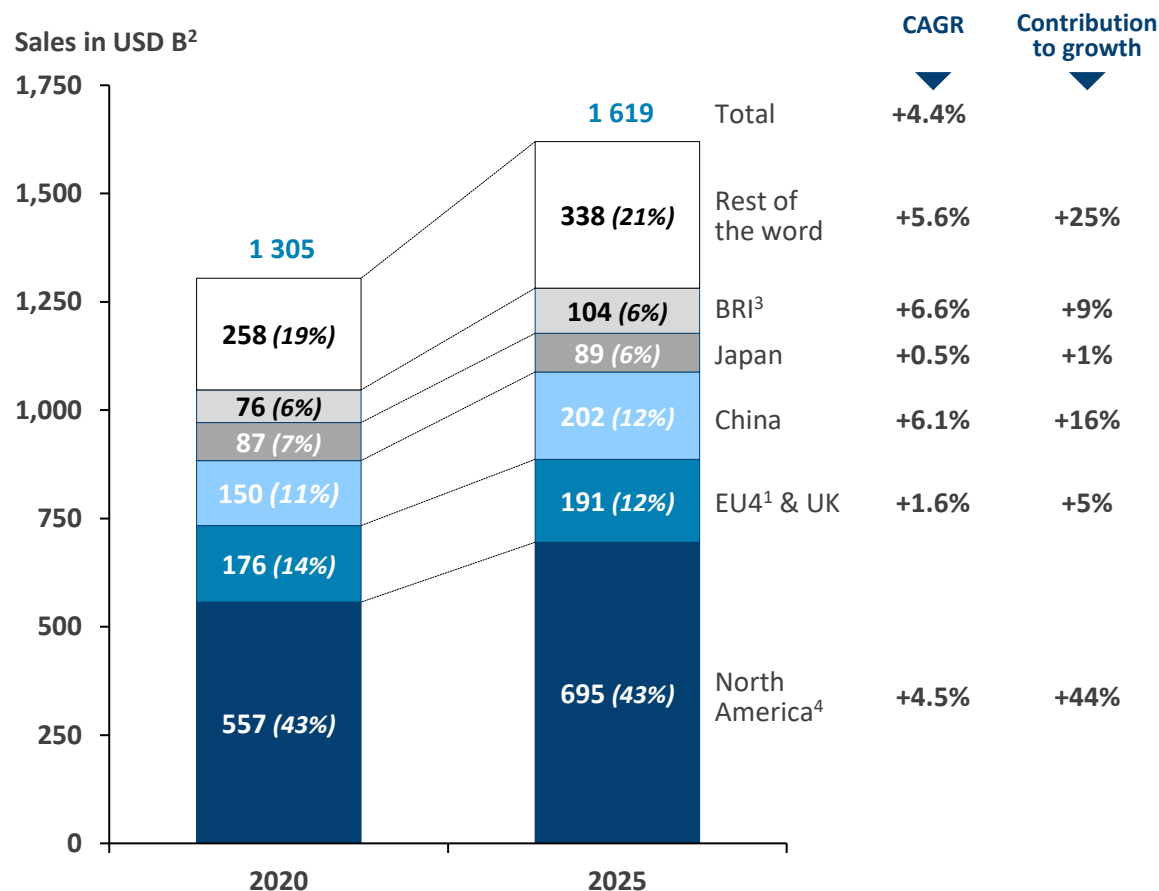
- 1** Population increase and ageing
- 2** Better access to medicines in emerging markets (e.g., BRICS¹, Mexico, Turkey, etc.) as a result of an increasing GDP per capita
- 3** Strong development of generics market (access to a larger number of people, especially in lower income countries), and to a lesser extent of biosimilars
- 4** Strong demand from patients / PAGs² for more effective and better tolerated new drugs



- 1** Decreasing R&D productivity of pharma companies re. breakthrough innovations
- 2** Increasing barriers to market access and stronger pressure on price from payers (governments, HMOs, patients, etc.), exacerbated by a tougher economic environment
- 3** Increasing competition of non-reimbursed drugs by medical devices and food supplements
- 4** Intensification of competition from generic and biosimilar drugs

Sales of EU4¹ & UK should grow slowly by 2025 due to stringent cost containment measures leading to a two-point decrease of their weight in the global pharmaceutical market

Global pharmaceutical market size and growth by geographic area (2020 – 2025)



- The global pharma market is expected to grow with a **CAGR of +4.4%** by 2025, including the impact of Covid-19, that should lead to **higher pressure on prices** worldwide, in the next 5 years
- **EU4 & UK** countries account together for only 14% of the global pharma market (Germany: 4%, France: 3%, Italy: 3%, UK: 2% and Spain: 2%) and should see their **weight drop by 2 points** by 2025, due to higher **price pressure** than in the average of the other countries in the world
- **North America** (of which the USA accounts from 41%) should continue to weigh for 43% of the global pharma market in value and contribute to **44% to worldwide market growth** over the 2020 – 2025 period
- **~75%** of the global pharmaceutical market **profits** which have been **generated by the USA** in 2020, should **reach ~80% in 2025**

By 2025, the French Pharma market is expected to step back from the 5th to the 6th place at the global level and remain at the 2nd place in Europe

Global pharmaceutical market ranking in value¹ (2015 – 2020 – 2025)

Rank	2015	2020	2025	CAGR 2020 – 2025
1	USA	USA	USA	++
2	China	China	China	+++
3	Japan	Japan	Japan	+
4	Germany	Germany	Germany	++
5	France	France	Brazil	++++
6	Italy	Italy	France	+
7	UK	UK	Italy	++
8	Spain	Brazil	UK	++
9	Canada	Spain	India	++++
10	Brazil	Canada	Russia	++++
11	India	India	Spain	++
12	South Korea	Russia	Canada	++
13	Russia	South Korea	South Korea	+++
14	Australia	Australia	Turkey	++
15	Saudi Arabia	Mexico	Mexico	++
16	Mexico	Saudi Arabia	Australia	++
17	Poland	Poland	Saudi Arabia	++
18	Switzerland	Turkey	Poland	++
19	Belgium	Belgium	Belgium	++
20	Netherlands	Taiwan	Egypt	+++

CAGR
2020 – 2025

++++ → ≥8%

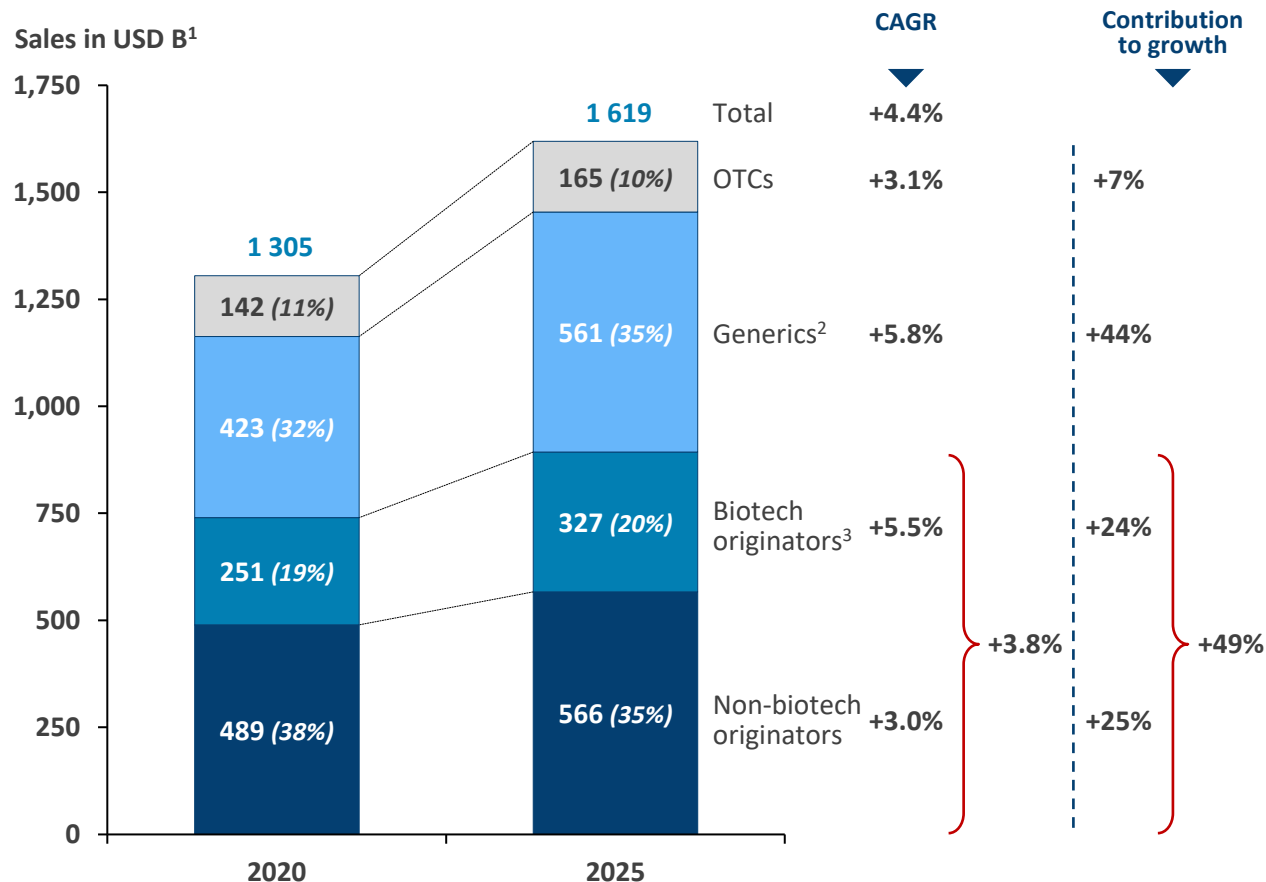
+++ → 6 – 7.9%

++ → 3 – 5.9%

+ → <0 – 2.9%

All the business segments of the pharma market will be affected by the Covid-19 crisis through a strong price pressure over the 2020-2025 period

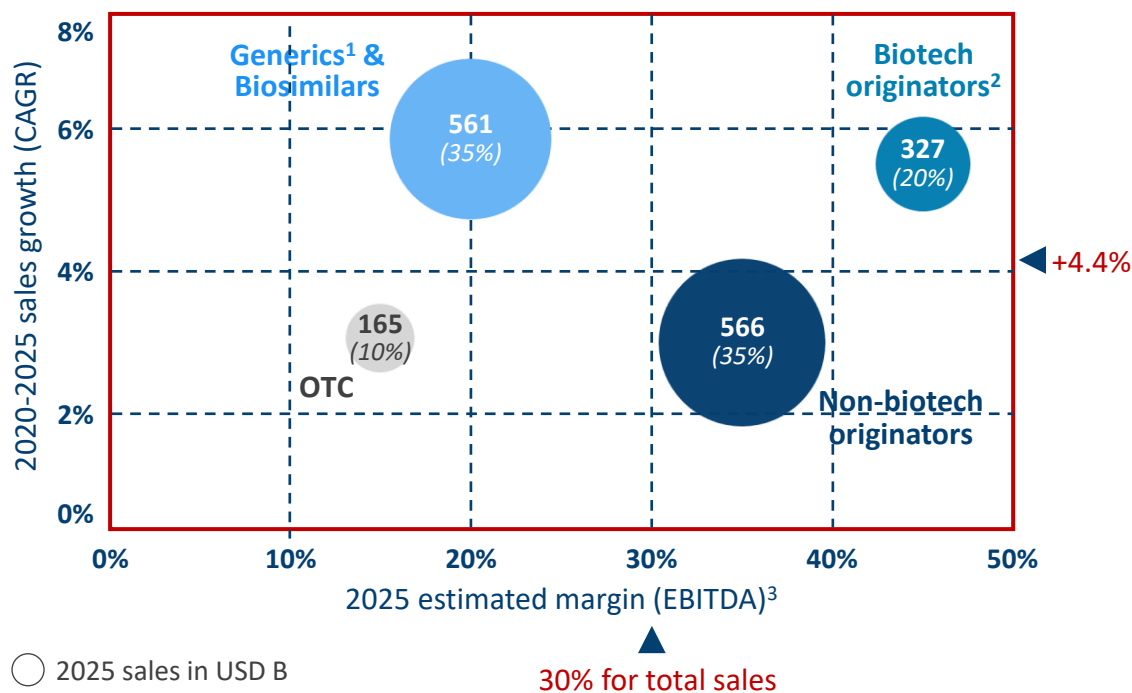
Global pharmaceutical market by strategic segment (2020 – 2025)



- **OTCs**, which should remain the smallest segment of the global pharma market, has been significantly **affected** by the **Covid-19** crisis in 2020, especially during **lockdown** periods. OTCs should grow at a lower pace than the other market segments, due to their stronger sensitivity to the economic environment
- **Generics** and **biosimilars** should continue to **grow** in **volume** due to patent expiries, but **pressure** on **prices** should **intensify** on this market segment
- **Biotech originators** should become the main **driver of innovation** in the next 5 years
- **Non-biotech originators** should be less dynamic, due to generics competition and the maturity of most of the brands. However, they should remain the **largest segment** of the global pharma market

By 2025, the sales growth of the pharma market should be essentially driven by generics and biotech originators, but pharma companies should lose two points of profitability

Global pharmaceutical market attractiveness by strategic segment (2020 – 2025)

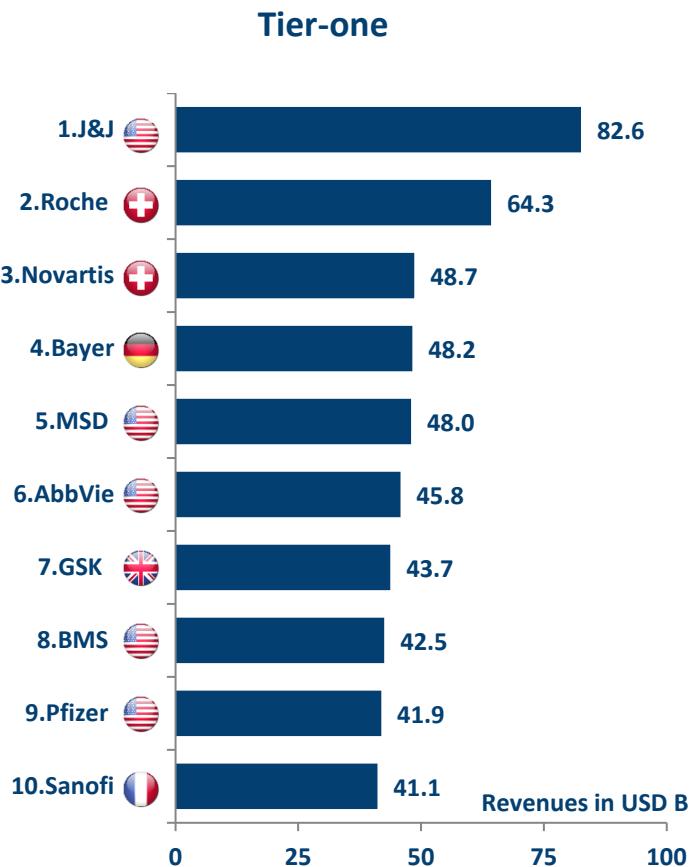


- By 2025, the **global pharma market** should reach USD 1,619 B and grow at a pace of **+4.4% per year**, i.e., 1.5 point of percentage above the forecasted worldwide economic growth, but **0.6 point below the pre-Covid-19 estimates**
- The average **EBITDA** of the pharma industry should **decrease** from ~32% in 2020 to ~30% in 2025, mainly as a result of increasing price pressure
- In 2025, the **average net profits** of pharma companies are expected to be **more than twice higher** than the average of all **other** business sectors
- The **biotech** segment will **remain very attractive** but **biosimilar** competition will ramp up
- The OTC segment should be the least attractive

Worldwide economic growth – CAGR 2020-2025: +2.9%

The top 20 pharma companies based on all segments of activities¹ counts
 10 companies from the USA, 8 from Europe, 1 from Japan and 1 from Israel

Top 20 pharma companies (2020) – All strategic segments



Sources: Companies annual reports (2020) – Pharmaceutiques (March 2021) – Smart Pharma Consulting analyses

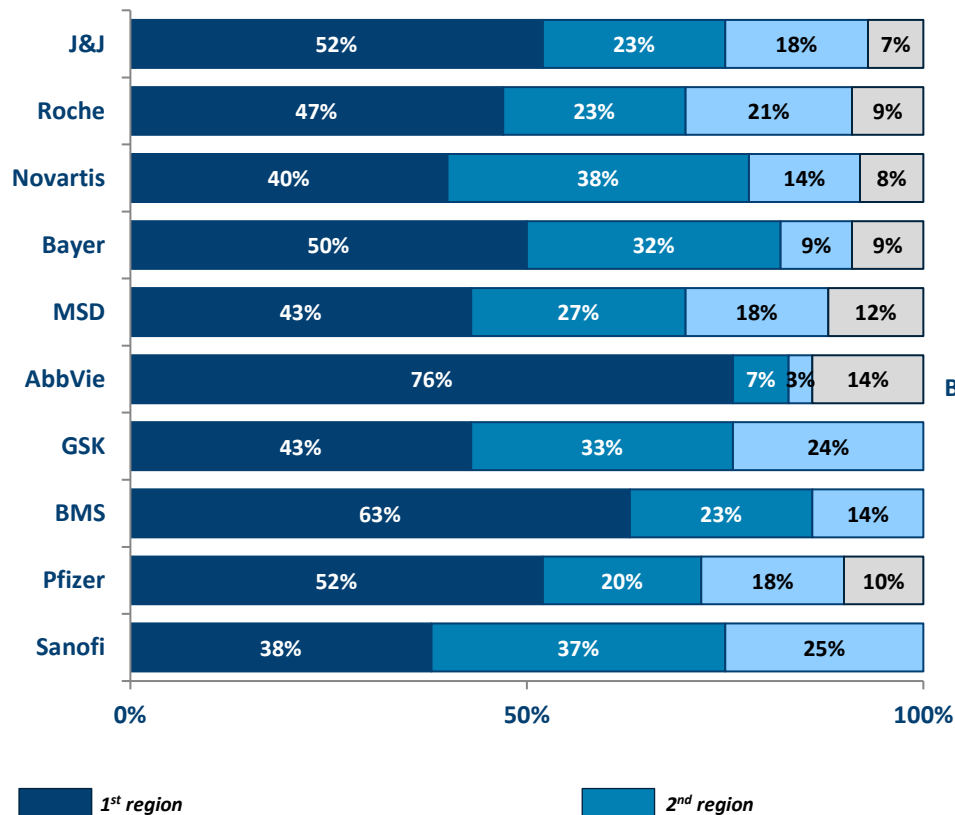
¹ Including Rx-bound drugs but also all other businesses (e.g., consumer healthcare, medical devices, food supplements, animal health) –

² Including mature brands business of Pfizer Upjohn merged with Mylan since November 16, 2020

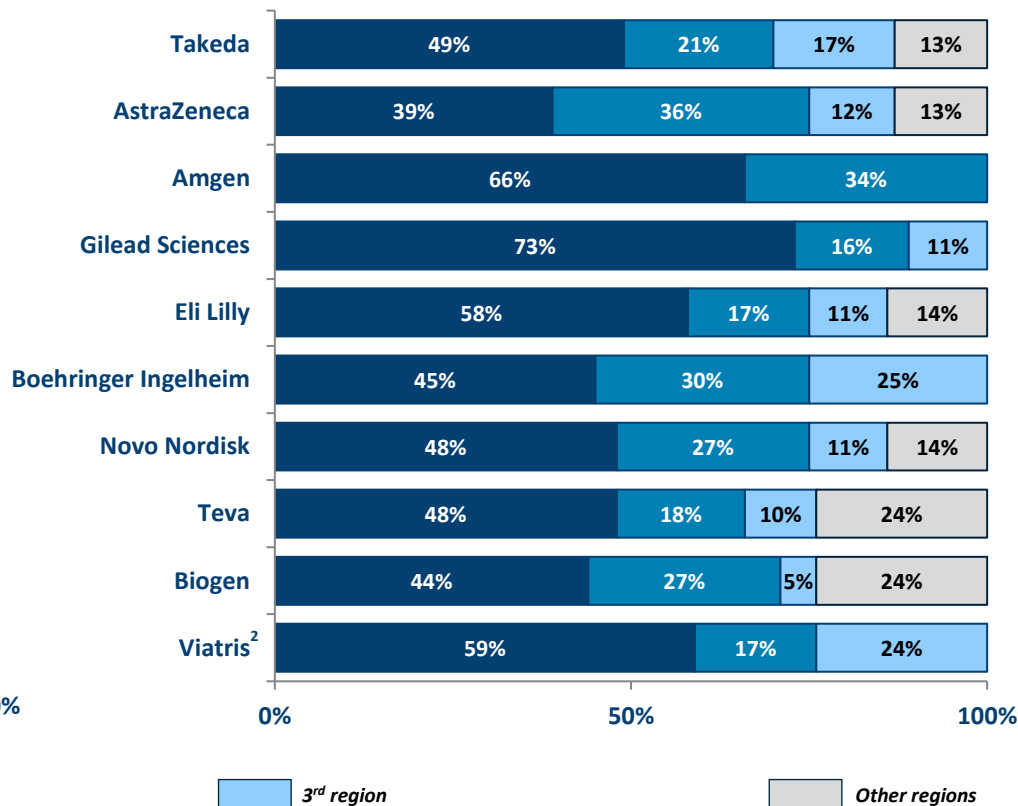
Tier-two pharma companies tend to be less geographically diversified, with most of them generating half of their revenues in a single region

Top 20 pharma companies – All strategic segments – Geographical areas (2020)

Tier-one



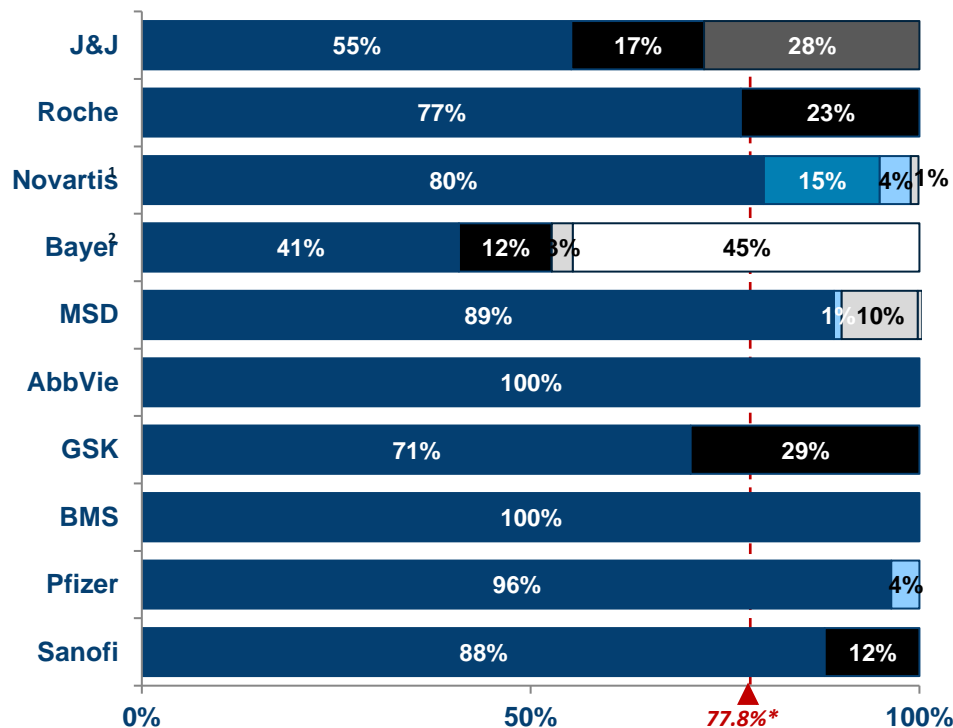
Tier-two



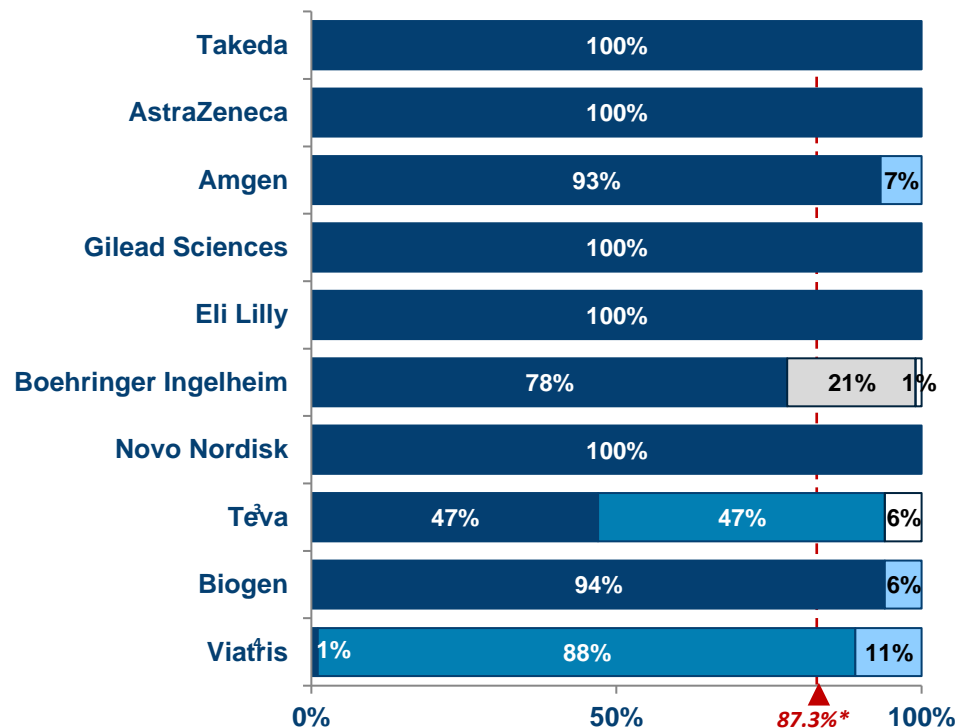
In 2020, original Rx-bound drugs and vaccines segments were the main source of revenue for most big pharma companies

Top 20 pharma companies – Strategic segments coverage (2020)

Tier-one



Tier-two



Prescribed drugs & vaccines in human health:



Other segments:

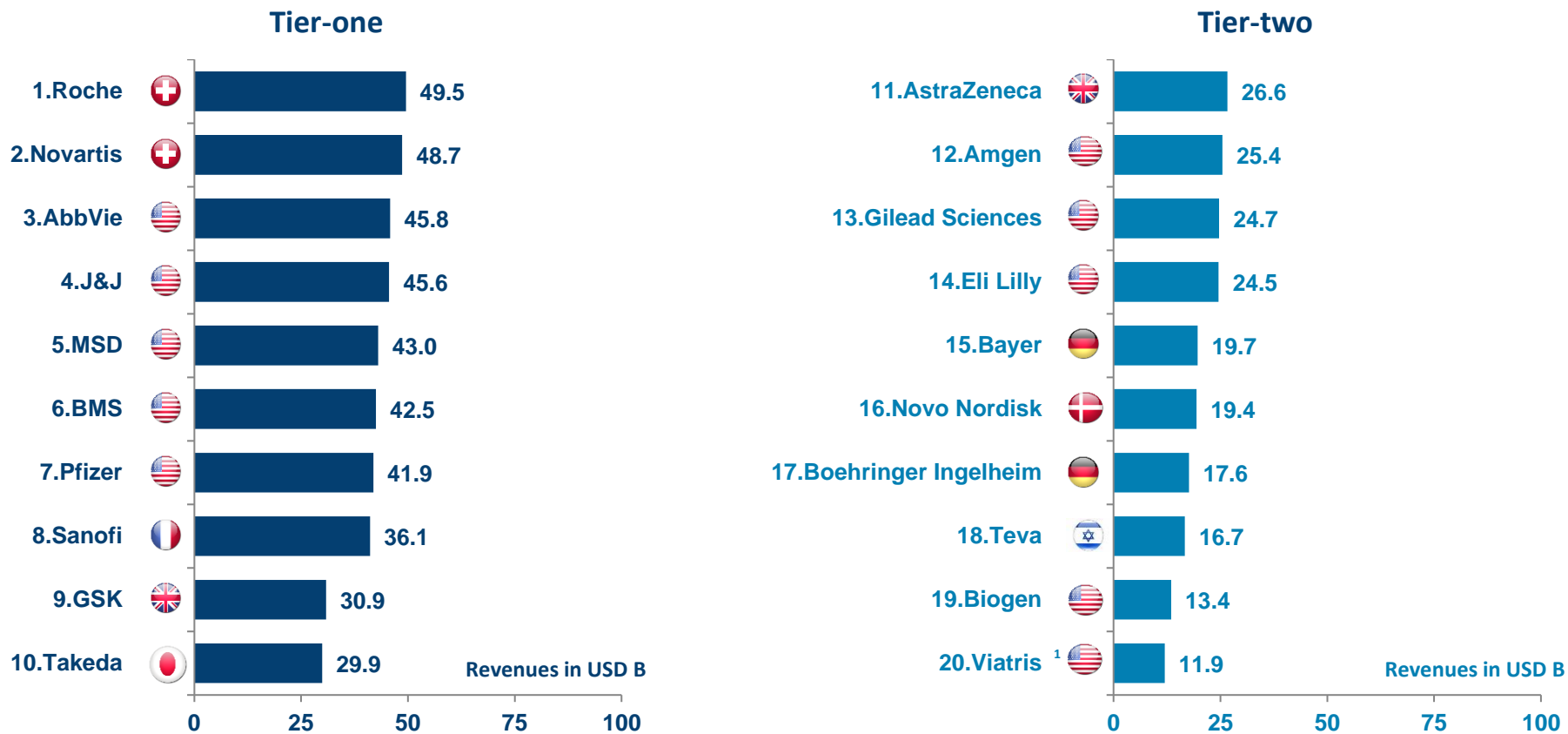


* Weighted average of the prescribed drugs and vaccines in human health

The top 20 pharma companies based on strategic drug & vaccines segments sales counts

10 companies from the USA, 8 from Europe, 1 from Japan and 1 from Israel

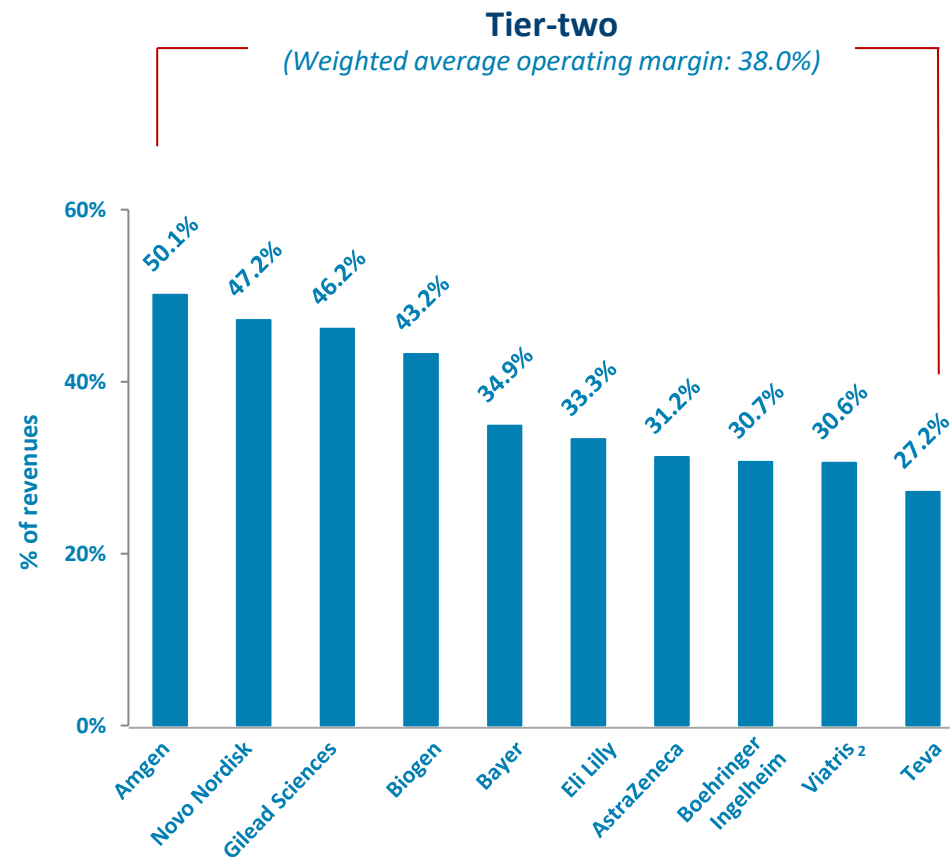
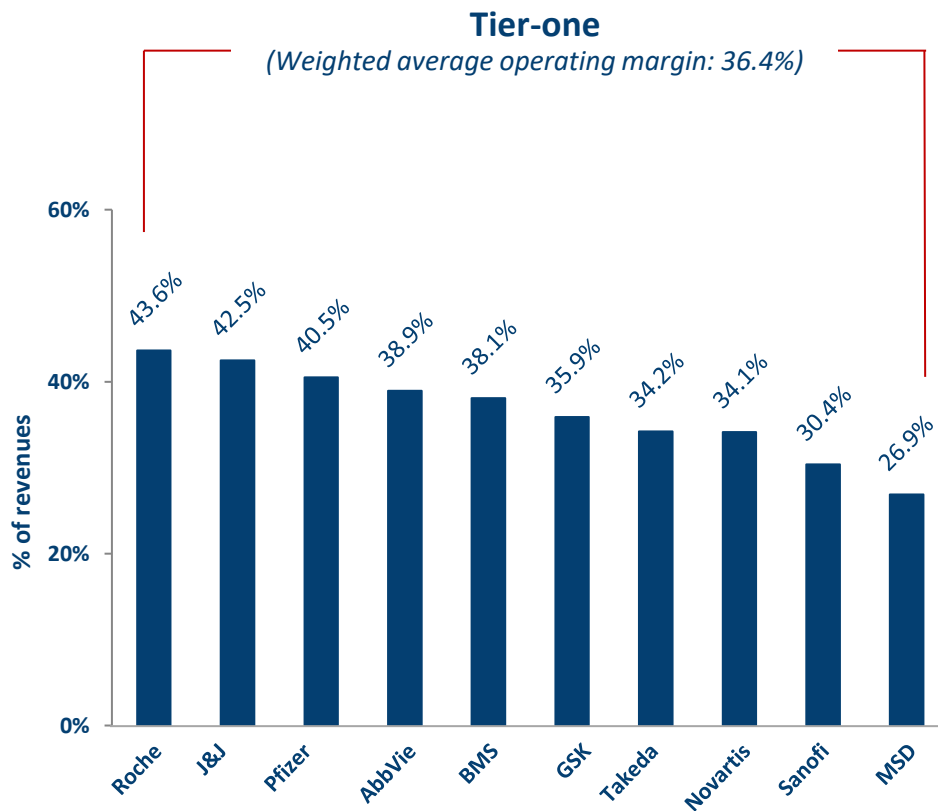
Top 20 pharma companies – Drugs & vaccines strategic segments (2020)



Note: panel of the 20 biggest pharma companies in terms of prescribed sales (drugs & vaccines) in human health in 2020 (excluding diagnostics, medical device, nutrition products and animal health)

The 2020 average operating margin was higher for tier-two companies in comparison to tier-one companies, with a similar dispersion profile

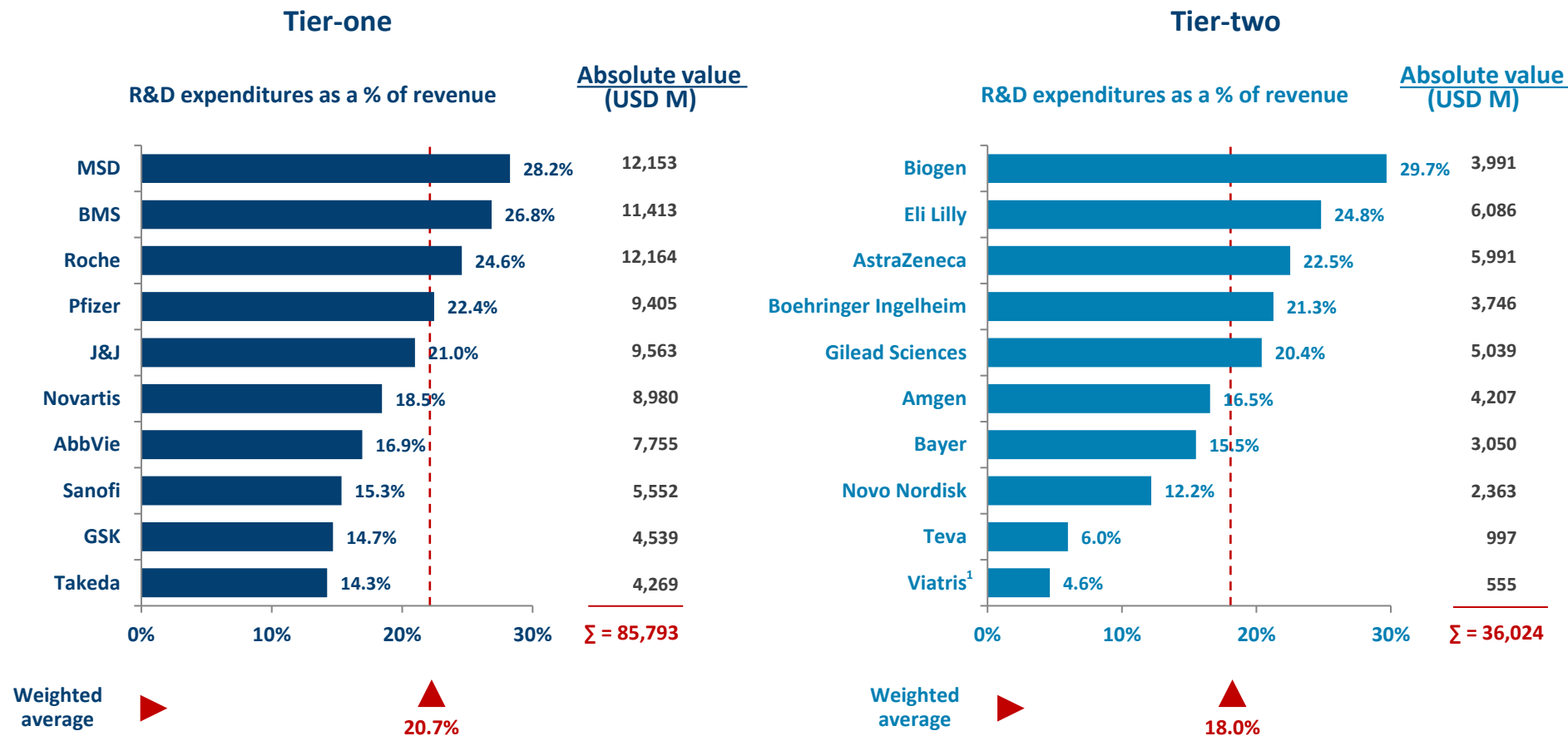
Top 20 pharma companies – EBITDA¹ (2020)



Note: panel of the 20 biggest pharma companies in terms of prescribed sales (drugs & vaccines) in human health in 2020 (excluding diagnostics, medical device, nutrition products and animal health)

Tier-one pharma companies have spent two times more for R&D in absolute value than tier-two pharma companies and ~2.7 points more as a percentage of their revenues

Top 20 pharma companies – R&D expenditures (2020)

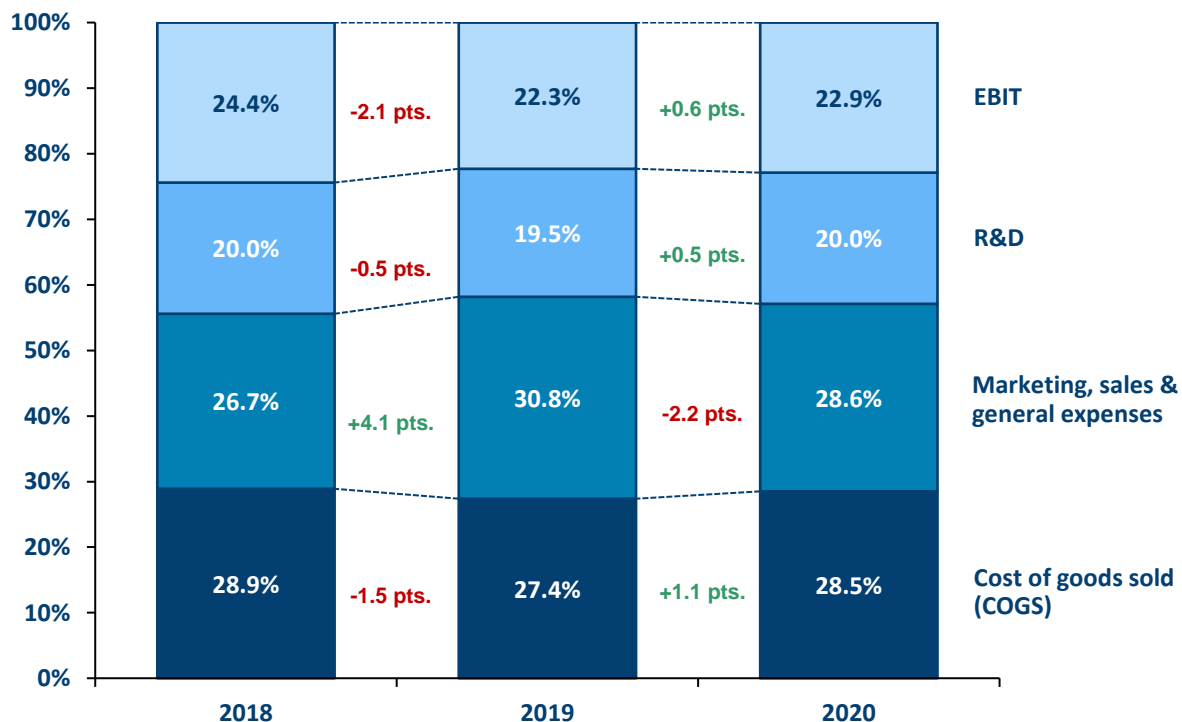


In 2020, the weighted average operating result (EBIT) of the top 20 pharma companies reached ~23% of revenues, decreasing by 1.5 point of percentage vs. 2018

Top 20 pharma companies – Cost structure (2018 – 2020)

Cost structure as a percentage of total revenues

Weighted average of total revenues



- The analysis of the top 20 pharmaceutical companies in the world shows that their average profitability has slightly decreased by 1.5 point of percentage between 2018 and 2020
- This negative trend can be explained by:
 - The price pressure imposed by healthcare authorities
 - The loss of exclusivity of many blockbusters that has led to the intensification of generics and biosimilars competition
- With an average operating result of ~23% in 2020, the level of performance remains high, which is the Achilles heel of pharmaceutical companies when negotiating price and reimbursement of their drugs with governments and payers
- In 2020, Marketing, sales & general expenses were 43% higher than investment in R&D

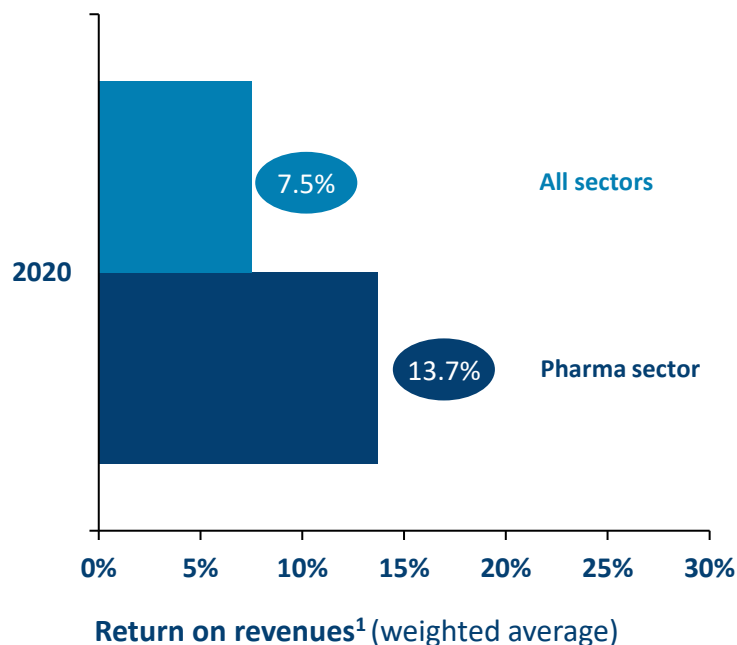
Note: panel of the 20 biggest pharma companies in terms of prescribed sales (drugs & vaccines) in human health in 2020 (excluding diagnostics, medical device, nutrition products and animal health)

In 2020, the net profitability of the pharma sector outpaces by
 ~6.2 points of percentage the average profitability of all sectors

Profitability and sales dynamics of the pharma sector (2018 – 2020)

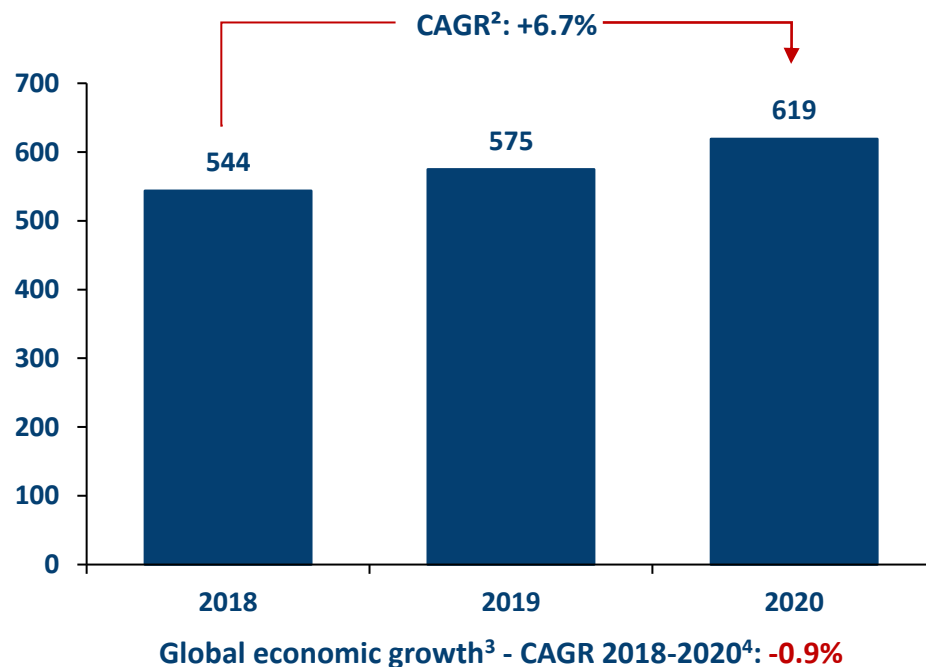
Net profitability in 2020

(Of top 20 Rx pharma companies and of the global economy)



Market sales trend

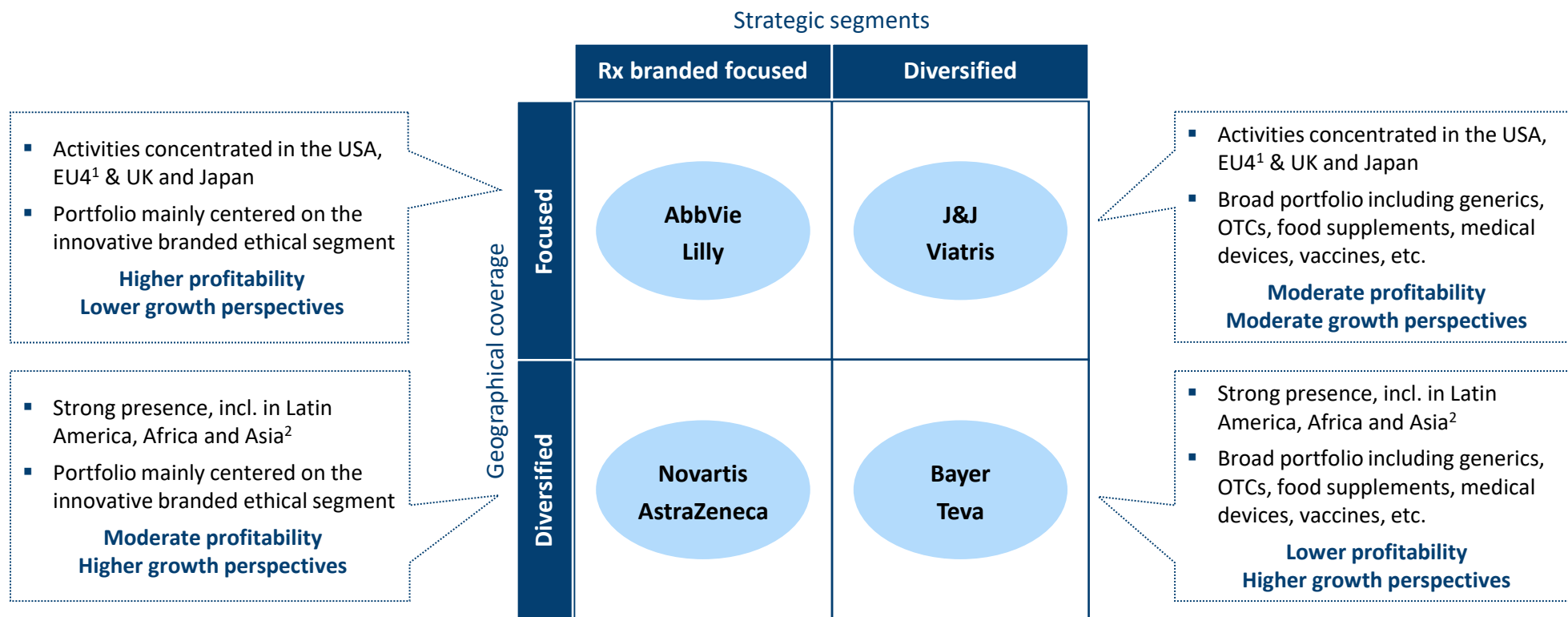
(Of top 20 Rx pharma companies)



Note: panel of the 20 biggest pharma companies in terms of prescribed sales (drugs & vaccines) in human health in 2020 (excluding diagnostics, medical device, nutrition products and animal health)

Best performers are focused on innovative Rx-bound drugs and generate an important share of their revenues from the USA, which is the most profitable and dynamic market

Development strategy matrix – Principles






*Note: **Rx branded focused**: Prescribed drugs and vaccines ≥ 75% of total product sales – **Geographically focused**: >50% of sales in a single geographical region (e.g., USA, Europe, Japan, etc.)*

Tier-one and tier-two companies are mainly focused on Rx branded segment, but tier-one companies are more geographically diversified

Pharma companies' development strategy (2020)

Tier-one

Strategic segments

		Rx branded Focused	Diversified
Geographical coverage	Focused	  	
	Diversified	   	 

Tier-two

Strategic segments

		Rx branded Focused	Diversified
Geographical coverage	Focused	  	
	Diversified	    	

Note: **Rx branded focused**: Prescribed drugs and vaccines $\geq 75\%$ of total product sales – **Geographically focused**: $>50\%$ of sales in a single geographical region (e.g., USA, Europe, Japan, etc.)

Most of the recent M&A operations have been carried out to strengthen pharma companies position on their core strategic segments

Major M&A operations (2016 – 2020)

Acquirer	Acquired (> USD 2.0 B)	Strategic objectives		
		Diversification	Strengthening	Expansion
J&J	▪ Actelion (<i>Pulmonary arterial hypertension</i>)		✓	
	▪ Momenta pharmaceuticals (<i>Biotechnology</i>)		✓	✓
	▪ Auris Health (<i>Medical device</i>)			✓
	▪ Abbott Medical Optics (<i>Products for dry & irritated eyes</i>)		✓	
Roche	▪ Sparks Therapeutics (<i>Gene therapies</i>)	✓		
Novartis	▪ Advanced Accelerator Applications (<i>Oncology</i>)		✓	
	▪ AveXis (<i>Gene therapies, rare diseases</i>)		✓	
	▪ Endocyte (<i>Cancer and inflammatory diseases</i>)		✓	
	▪ The medicine company (<i>Critical care</i>)		✓	
Bayer	▪ Monsanto (<i>Chemical & agricultural biotechnology</i>)	✓		
	▪ Asklepios Biopharmaceutical (<i>Gene therapies for genetic disorders</i>)		✓	
MSD	▪ Antelq (<i>Animal health</i>)		✓	
Abbvie	▪ Stemcentrx (<i>Oncology</i>)		✓	
	▪ Allergan (<i>Branded pharmaceuticals</i>)	✓		
GSK	▪ Tesaro (<i>Oncology</i>)		✓	
	▪ Stiefel (<i>Dermatology</i>)	✓		
BMS	▪ IFM Therapeutics (<i>Cancer immunotherapies</i>)		✓	
	▪ Celgene (<i>Oncology</i>)		✓	
	▪ MyoKardia (<i>Rare cardiovascular disease</i>)	✓	✓	

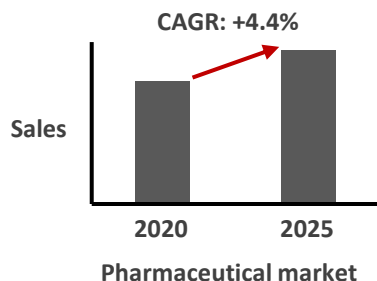
Acquirer	Acquired (> USD 2.0 B)	Strategic objectives		
		Diversification	Strengthening	Expansion
Pfizer	▪ Medivation (<i>Oncology</i>)		✓	
	▪ Anacor (<i>Anti-inflammatory</i>)	✓		
	▪ ArrayBioscience (<i>Oncology</i>)		✓	
Sanofi	▪ Boehringer Ingelheim (<i>Consumer healthcare business of the company</i>)		✓	
	▪ Bioverativ (<i>Rare blood disorders</i>)		✓	
	▪ Ablynx (<i>Immunotherapies</i>)		✓	
	▪ Principia BioPharma (<i>Oral therapies in immunology & oncology</i>)	✓	✓	
Takeda	▪ Synthorx (<i>Biotechnology</i>)			
	▪ Ariad Pharmaceuticals (<i>Oncology</i>)		✓	
AstraZeneca	▪ Shire (<i>Rare diseases, US-based</i>)		✓	✓
	▪ Acerta Pharma (<i>Cancer and autoimmune diseases</i>)		✓	
Amgen	▪ Alexion Pharmaceuticals (<i>Rare disease, US-based</i>)		✓	
	▪ Otezla (<i>Dermatology</i>)		✓	
Gilead Sciences	▪ Kite Pharma (<i>Cancer immunotherapies</i>)		✓	
	▪ Forty Seven (<i>Cancer immunotherapies</i>)		✓	
	▪ Immunomedics (<i>Cancer treatment</i>)		✓	
Eli Lilly	▪ Loxo Oncology (<i>Oncology</i>)		✓	
Boehringer Ingelheim	▪ Merial (<i>Animal health business of Sanofi</i>)		✓	
Teva	▪ Actavis Generics (<i>Allergan generics</i>)		✓	
	▪ Rimsa (<i>Latin America</i>)			✓
Viatris	▪ Meda (<i>OTC, Emerging markets</i>)	✓		✓
	▪ Upjohn (<i>Pfizer's established medicines</i>)		✓	

Note: Diversification means entering new strategic segments/balancing minor segments – Strengthening means reinforcing major strategic segments – Expansion means geographical coverage

The global pharmaceutical market should keep on growing at a pace of 4.4% p.a. by 2025, but pharma companies' profitability would be impacted by strong price cuts

Conclusion (1/2)

Global pharma market
2020-2025 perspectives



The global pharma market should reach USD 1,619 B in 2025, representing a +4.4% CAGR over the 2020-2025 period

- North America should continue to weigh for 43% of the global pharma market in value and should generate ~80% of the global pharmaceutical market (vs. ~75% in 2020)
- EU4¹ & UK countries should see their weight in the global pharma market drop by 2 points from 14% to 12% due to stringent cost containment measures
- All the business segments will be affected by the pandemics-induced economic crisis, resulting into strong price pressure

Top 20 pharma companies
Performance & Strategies

EBITDA ²	37% of sales	EBIT ³	~23% of sales	R&D	~20% of sales
---------------------	--------------	-------------------	---------------	-----	---------------

Strategic segments

		Rx branded focused	Diversified
Geographical coverage	Focused	      	 
	Diversified	        	  

To improve their performance, pharma companies tend to refocus on therapeutic areas with high potential for growth (e.g., rare diseases, oncology, gene and cellular therapies)

Conclusion (2/2)

- In recent years, mega-deals aiming at increasing pharma companies' size and/or strengthening their economies of scale have come to an end
- Pharma companies rather seek to refocus their assets on secondary-care therapeutic areas with high potential for growth:
 - Rare diseases (e.g., acquisition of Shire by Takeda or of Alexion by AstraZeneca, etc.)
 - Oncology (e.g., merger of Celgene and BMS, acquisition of Stemcentrx by AbbVie and partnership of the latter with Genmab, etc.)
 - Gene and cellular therapies (e.g., partnership of Biogen with Sangamo, etc.)
- Top-pharma companies increasingly seek to acquire promising early-stage development biotech companies with the aim to add complementary platforms and technologies...
- ... and tend to foster their collaborations with other pharma companies, notably in the Covid-19 context (e.g., Pfizer / BioNTech, GSK / Sanofi, AstraZeneca / Oxford University, etc.)
- Conversely, divestments are made in other areas (e.g., separation by Pfizer of its Upjohn mature brands division merged with Mylan into the new Viatris, rethinking by Sanofi of its core activities, sale by GSK of its Consumer Healthcare division¹)

Pharma Strategy Crafting

BEST-IN-CLASS SERIES

A practical guide

Strategy sets long term direction and scope of a company to achieve a competitive advantage through proper capability building and resources allocation

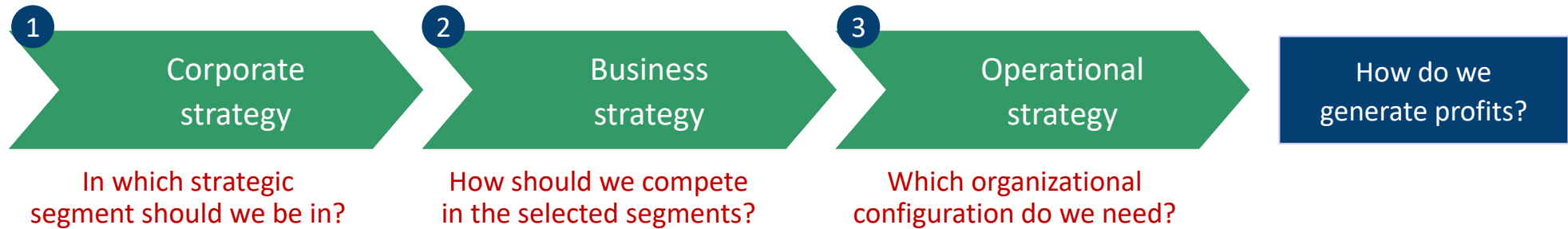
Strategy definition

- Strategy is a **consistent, unifying and integrative assembly** of decisions defined to **achieve the ambition** and the corresponding **objectives set** by a company, in the **most effective, efficient and less risky manner**
- It attempts to achieve the **long-term sustainable advantages** the company can maintain in its businesses, by responding to the present and future **opportunities and threats** in the market segments it covers, through the optimal management of its **strengths and weaknesses**
- It is concerned with the definition of **optimal capabilities** and **resources** configuration to **take advantage**, better than competition, of the **evolving customers needs and wants**
- It **covers** the **responsibilities** and **actions** required from **all hierarchical levels** (corporate, business, operational) in the firm
- It **defines** the nature of the **economic** and **non-economic contributions** the company intends to make to its stakeholders

“A successful strategy meets or, better, exceeds customers, employees and shareholders expectations to raise their respective preference for the company, its products and associated services”

Corporate strategy selects the strategic segments, business strategy creates a competitive advantage and operational strategy defines the appropriate organization

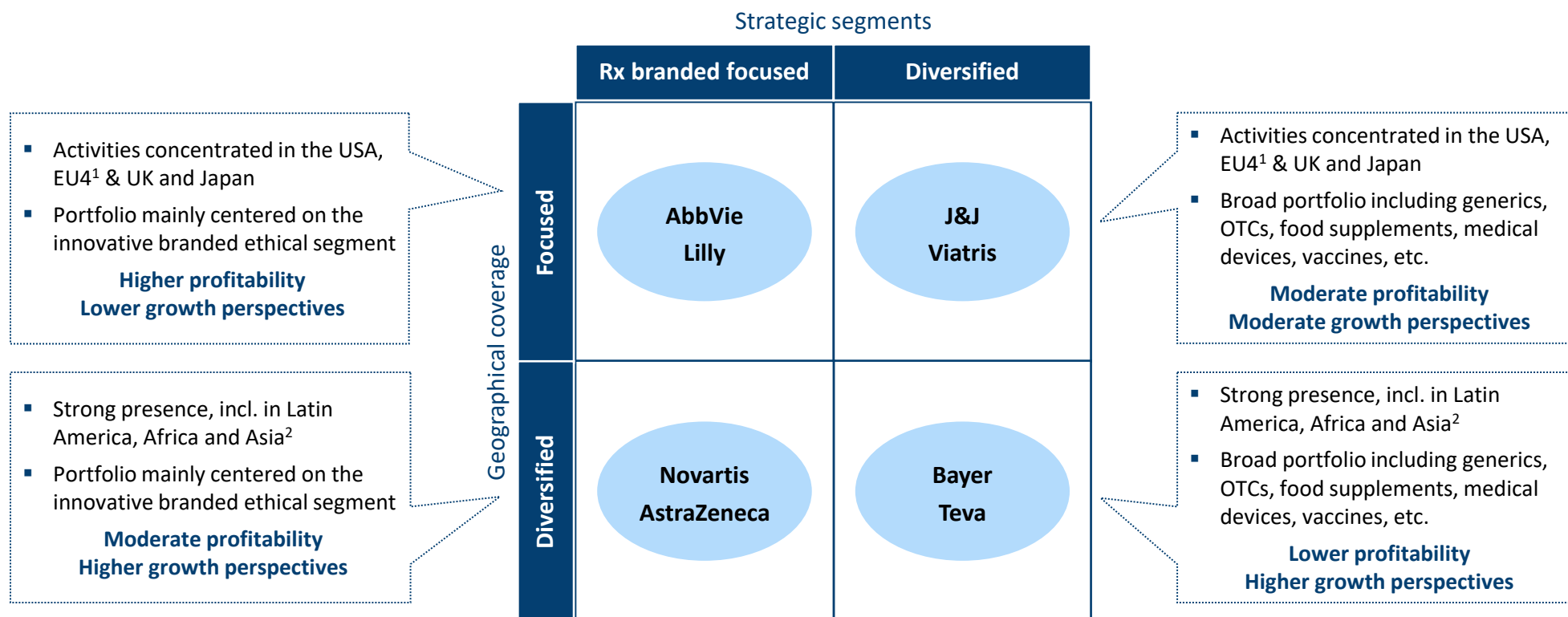
Multi-level Strategies



- **Corporate strategy** defines the purpose and the scope in which a company competes or should compete and how value will be added to its different businesses
- **Business** or **competitive strategy** is concerned with how to compete successfully within particular strategic segments (e.g., original brands, generics, OTCs, medical device, etc.)
- **Strategic segments** correspond to companies within an industry which are subject to the same critical success factors which are addressed by a given business unit of the company
- **Operational strategy** determines the activities, capabilities, processes, structure¹, culture and resources needed to effectively support the corporate- and business-level strategies

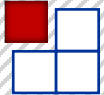
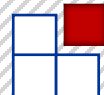

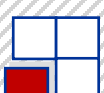
Concentration strategies use to generate higher profitability ratios, whereas diversification and geographical expansion strategies provide higher profit growth

Development strategy matrix: Principles



Even if there is no one-size-fits-all winning strategy, a “global healthcare” strategy seems to be a reasonable long-term default option for Big Pharma companies

Development strategy matrix: Features

Strategic development directions	Sales evolution*	Profitability evolution*	Profit evolution*	Recommendations
 Local ethicals	+	--	++	<ul style="list-style-type: none"> Strategy showing the highest return on investment Moderately risky if portfolio of breakthrough innovations Reservoir of sales growth on the lower priced me-too markets (e.g., Amgen entering the biosimilars market)
 Local healthcare	++	--	++	<ul style="list-style-type: none"> Diversification in new strategic segments should be carried out preferably through acquisitions to save time, take advantage of brand equity (especially in the OTC market), know-how, and access to clients
 Global healthcare	+++	---	+++	<ul style="list-style-type: none"> Portfolio diversification is best implemented through the acquisition of global players (e.g., Pfizer and Hospira) Geographical expansion is preferable through the acquisition of local leaders (e.g., Teva and Rimsa)
 Global ethicals	++	---	++	<ul style="list-style-type: none"> Geographical expansion implies an “aggressive” direct or indirect presence (through licensing-out deals) Social “expansion” requires a tiered pricing policy or low-priced products to access low-income patients

* +++ Highly positive ++ Moderately positive + Slightly positive --- Highly negative -- Moderately negative - Slightly negative

Tier-one and tier-two companies are mainly focused on Rx branded segment, but tier-one companies are more geographically diversified

Pharma companies' development strategy (2020)


Tier-one

Strategic segments

		Rx branded Focused	Diversified
Geographical coverage	Focused	  	
	Diversified	   	 

Tier-two

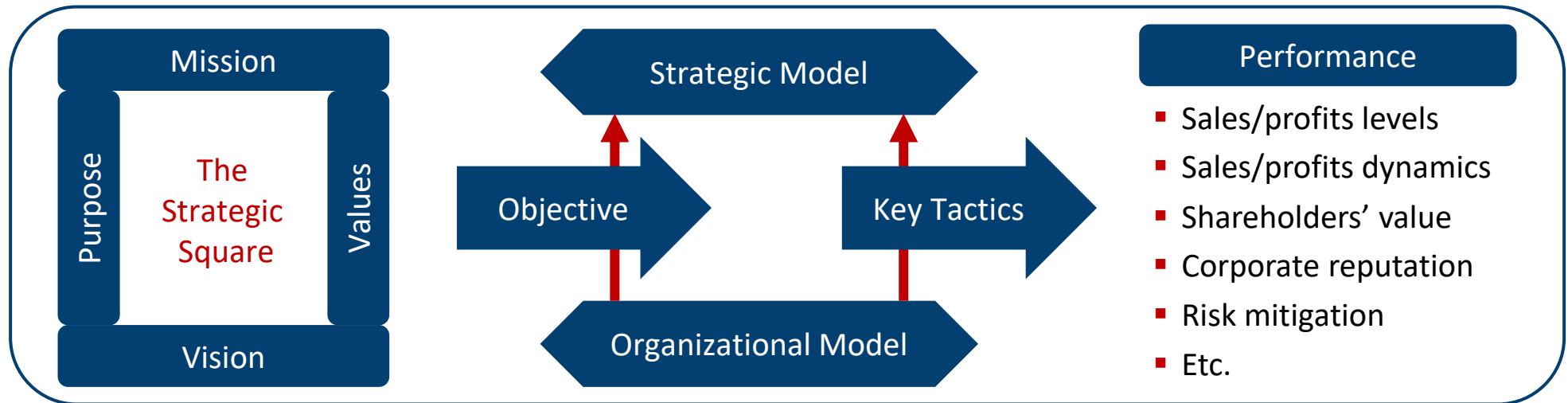
Strategic segments

		Rx branded Focused	Diversified
Geographical coverage	Focused	  	
	Diversified	    	

Note: Rx branded focused: Prescribed drugs and vaccines $\geq 75\%$ of total product sales – **Geographically focused:** $>50\%$ of sales in a single geographical region (e.g., USA, Europe, Japan, etc.)

This strategic process should help pharma companies translate their “Strategic Square” into the right strategy and tactics supported by the right organization

Methodology: Smart strategic process



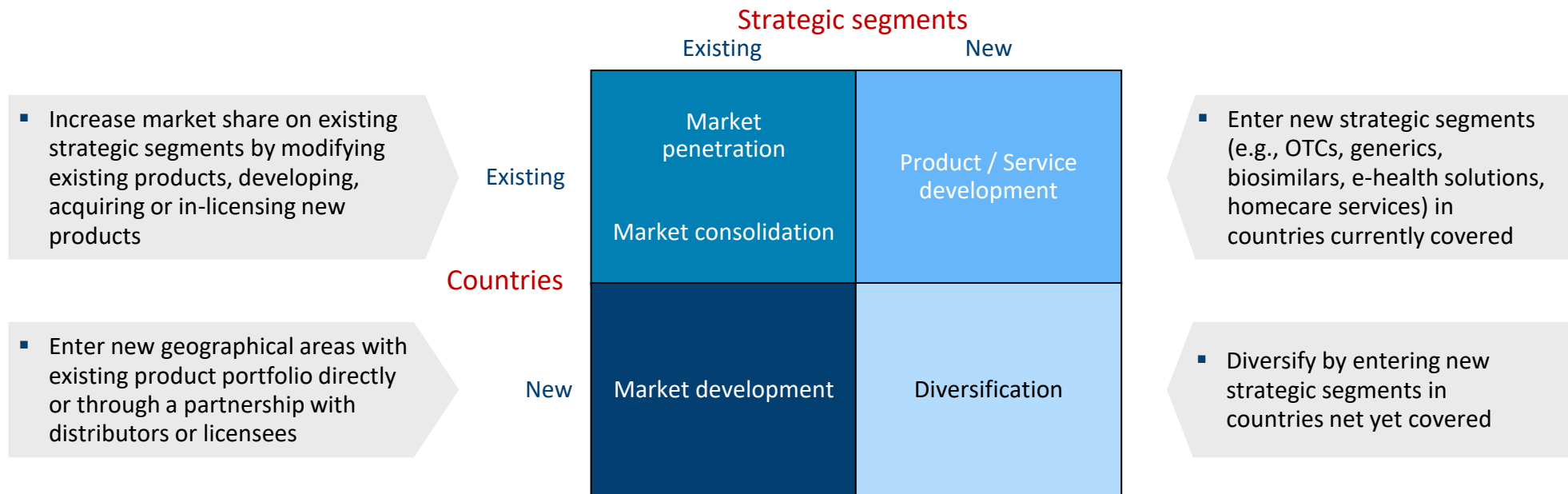
- **Purpose:** Why do we exist?
- **Vision:** What do we aspire to become?
- **Mission:** What do we do and for whom?
- **Values:** What do we believe in and how do we behave?
- **Objective:** What do we want to achieve?

- **Strategic model:** Where do we want to play and how are we going to play to win?
- **Organizational model:** What are the activities/capabilities, the processes, the structure¹ and culture we need to 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?

Four basic corporate strategies can be adopted by pharma companies to secure a long-term and profitable growth, in line with their shareholders expectations

Corporate strategy crafting (1/2)

- The Development strategy matrix is a practical tool to select the most attractive sources of growth
- Diversification is in general the riskiest option because the farthest from the company core competencies
- However, playing in diverse strategic segments with different characteristics can enable to mitigate business risks



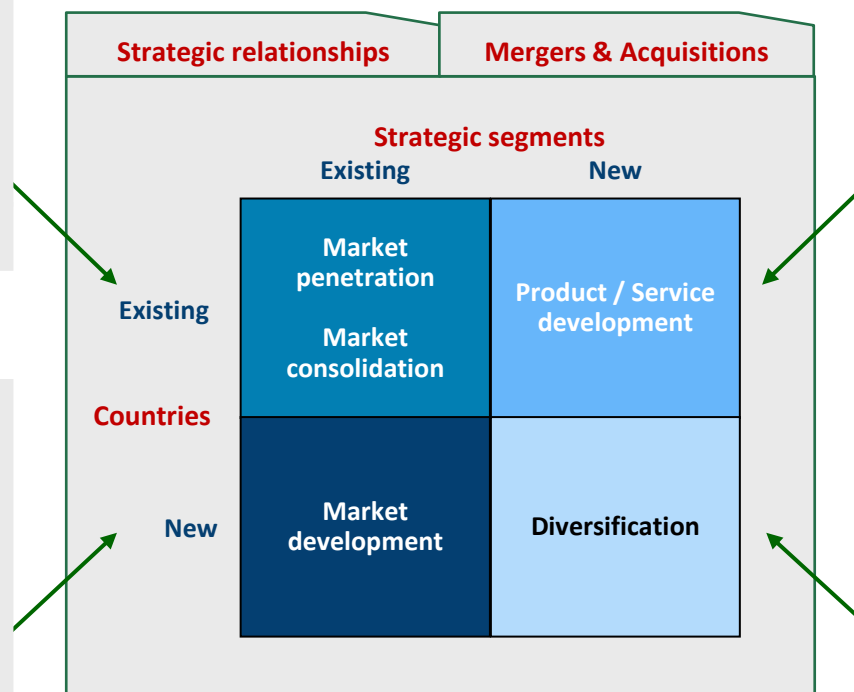
“The purpose of corporate strategy is to decide where to play and how to play to succeed”

The corporate strategy can be implemented by pharma companies organically or inorganically, through strategic partnerships, mergers or acquisitions¹

Corporate strategy crafting (2/2)

- Collaboration with a third party (e.g., pharma company and/or CSO²) to increase share of contacts and/or share of voice
- Co-marketing or co-promotion agreements to increase resources to market a product
- Acquisition of competitors to reduce or better manage competitive intensity

- Direct market entry by setting up its own subsidiary
- Indirect market entry by licensing-out its product portfolio to a third party or with a CSO
- Indirect market entry by acquiring a local player to take advantage of its resources and capabilities



- Entry on new strategic segments can be carried out through in-house R&D and/or through:
 - Horizontal integration (e.g., OTC, generics, homecare services)
 - Downward integration (e.g., distribution business)
 - Upward integration (e.g., toll manufacturing business)
 - Outsourcing to a CRO³
 - Etc.

- New strategic segments entry and new geographical coverage can be carried out organically or through acquisition, merger, joint-venture, in-licensing (e.g., with a pharma company) or subcontracting (e.g., with a pharma company, a CSO, a CRO) agreements

To craft a successful strategy, pharma companies must evaluate their business environment to identify where their competitive advantage will be the strongest

Business strategy crafting (1/3)

- To create a successful business strategy, pharma companies should carefully evaluate the strategic segment landscape they play in by:

Customers

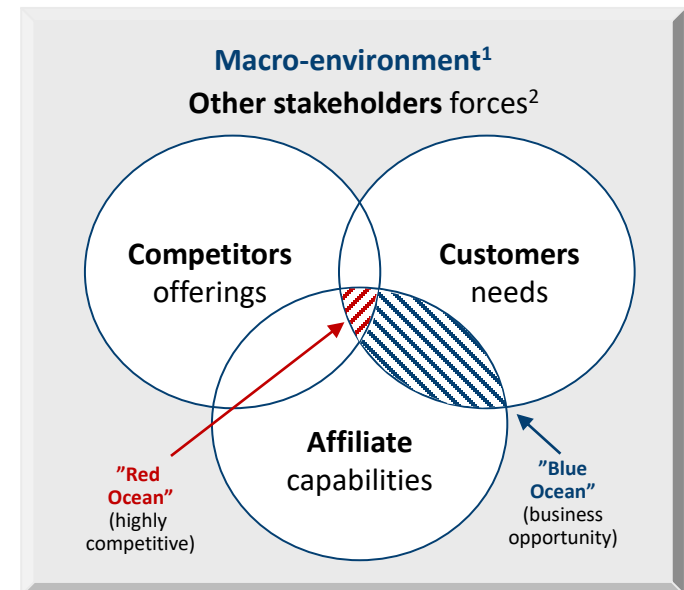
- Developing a detailed understanding of customer needs / wants
- Segmenting and targeting customers
- Identifying unique ways of creating superior value for customers

Competitors

- Analyzing competitors' current strategies, their impact, and predicting how they might change in the future

Company

- Providing products and services fulfilling better than competition, tangible and intangible customers needs / wants
- Finding strategic spaces or “blue oceans” that align the company’s capabilities with customer unmet needs and...
- ... raising barriers to prevent competitors to enter

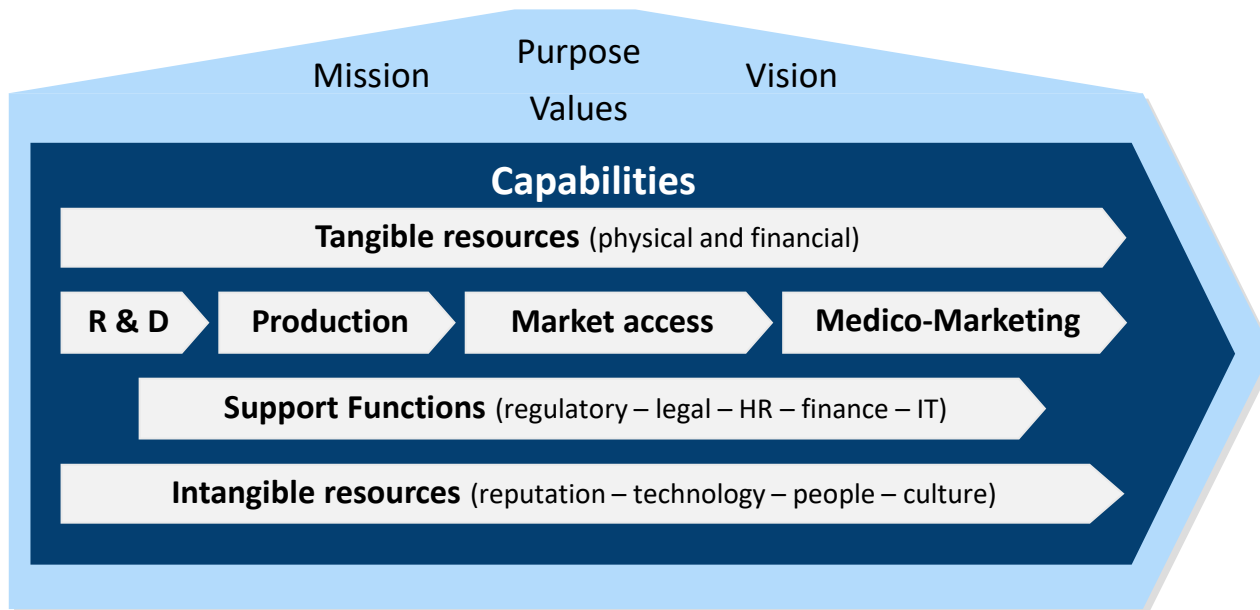


“Don’t just give customers excellent services, make sure they realize how great is the service they get”

The business strategy must offer a value proposition that meets, better than competition, customers needs and wants, by mobilizing capabilities and resources

Business strategy crafting (2/3)

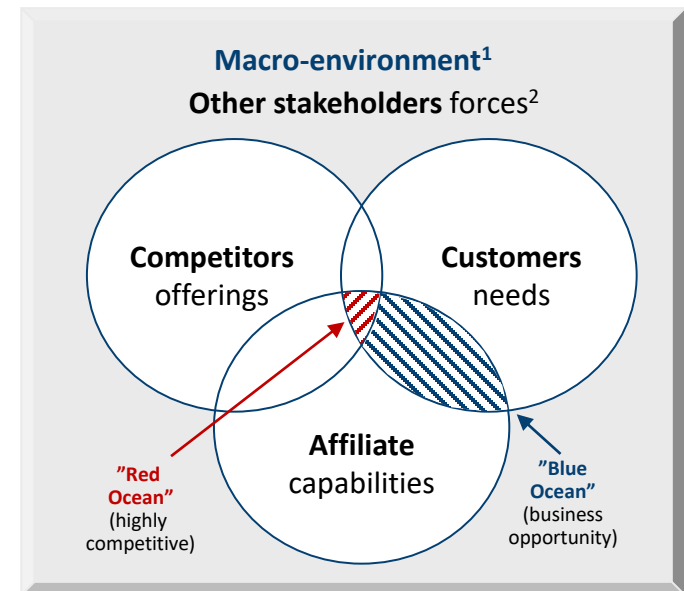
Business model



Strengths & Weaknesses
 (Competitive advantage)

Strategic segments

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



Opportunities & Threats
 (Attractiveness & Key success factors)

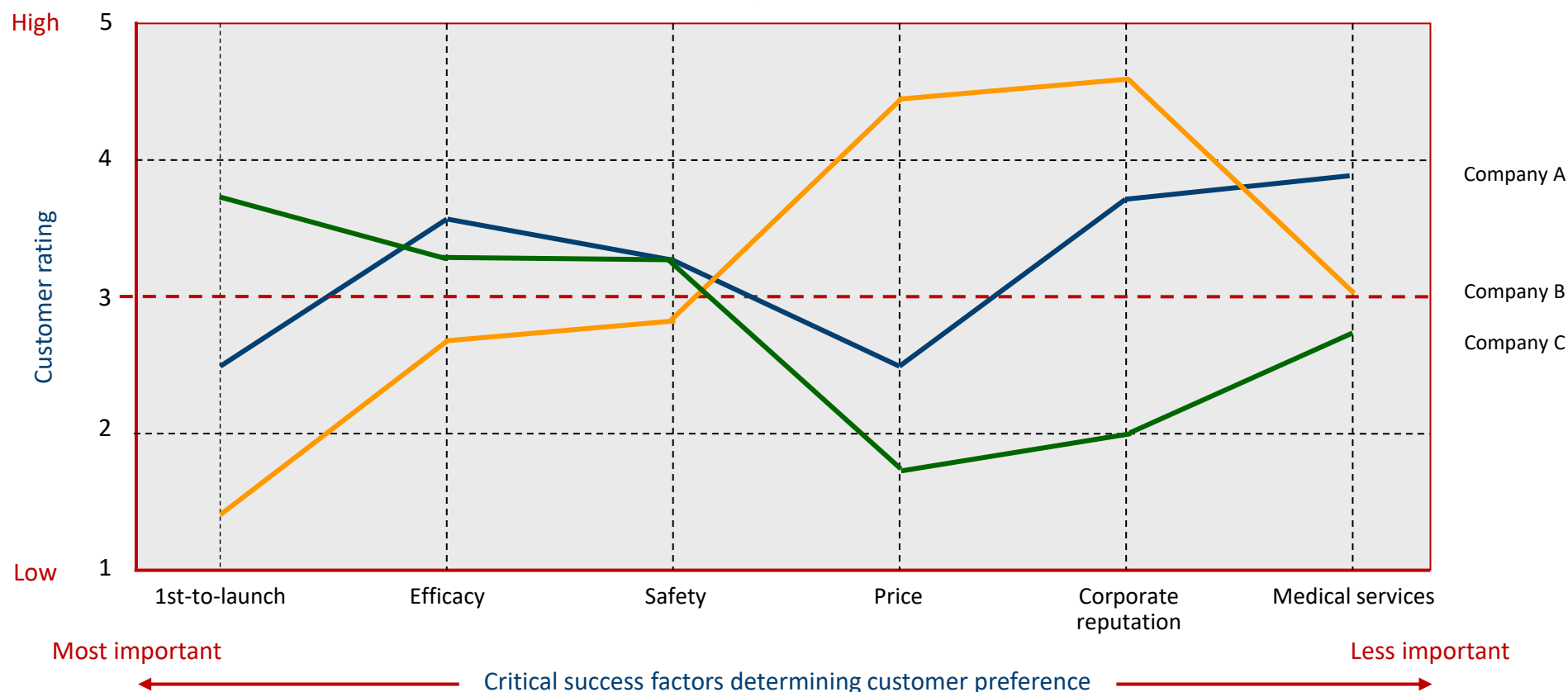
Objectives & Strategic priorities

The strategic canvas can help identify strategic gaps which represent opportunities that are not being fully exploited by competition

Business strategy crafting (3/3)

Strategic canvas

Illustrative

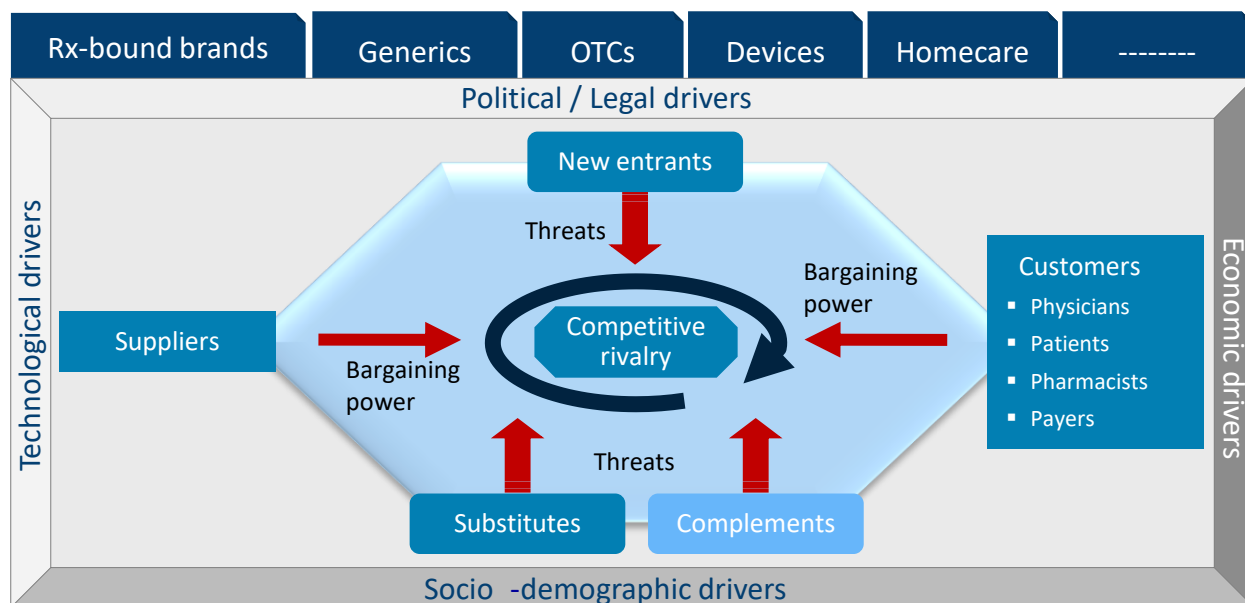


Source: Adapted after C. Kim et R. Mauborgne 2005

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

Business opportunities by strategic segment (e.g., original Rx-bound drugs, generics, OTCs, etc.) can be assessed through PEST analysis and the “5+1 forces framework”

Business strategy – Attractiveness of strategic segments (1/3)



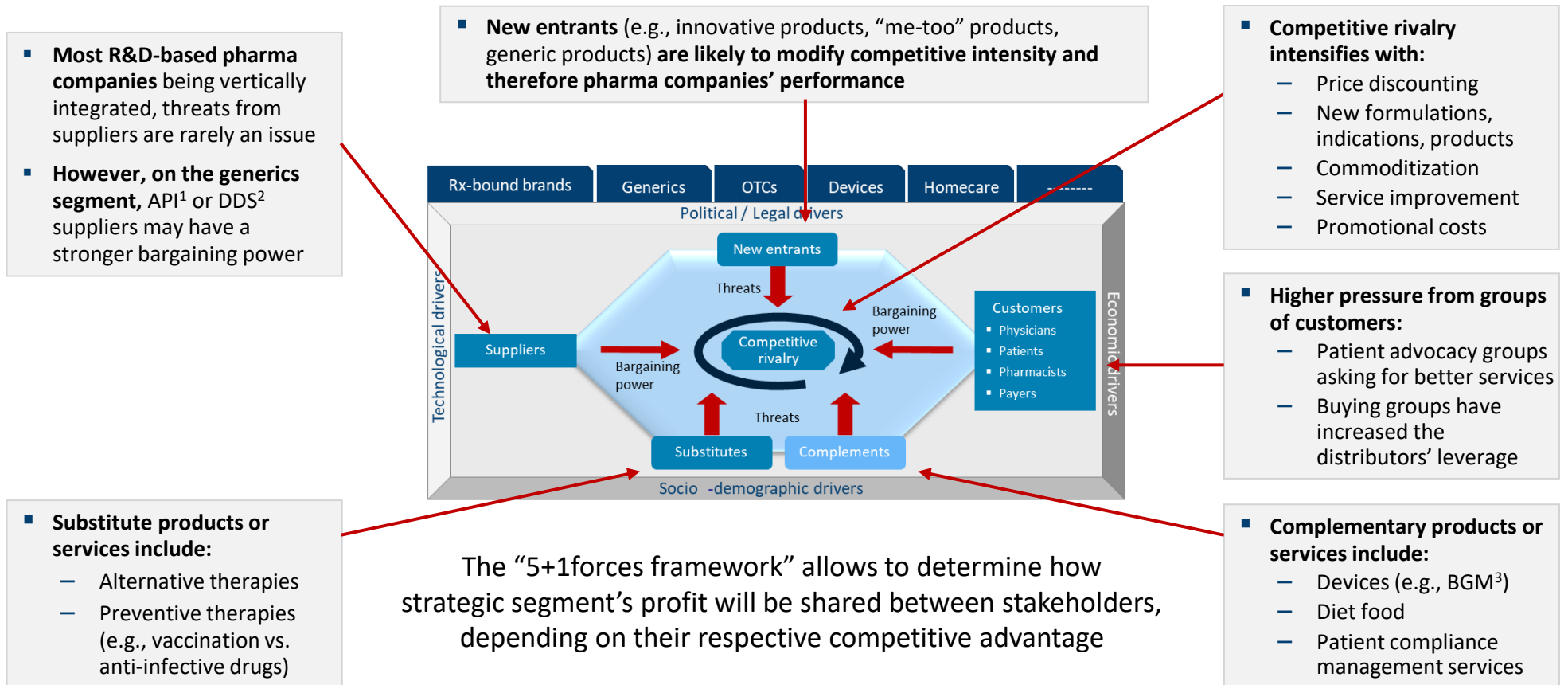
- The four key macro-environmental drivers:
 - Political / Legal
 - Economy
 - Socio-demography
 - Technology
- The five key micro-environment drivers:
 - Suppliers
 - Customers
 - New entrants
 - Substitutes
 - Competitive rivalry
- ... plus, the “Complements” influence the attractiveness of each strategic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

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

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

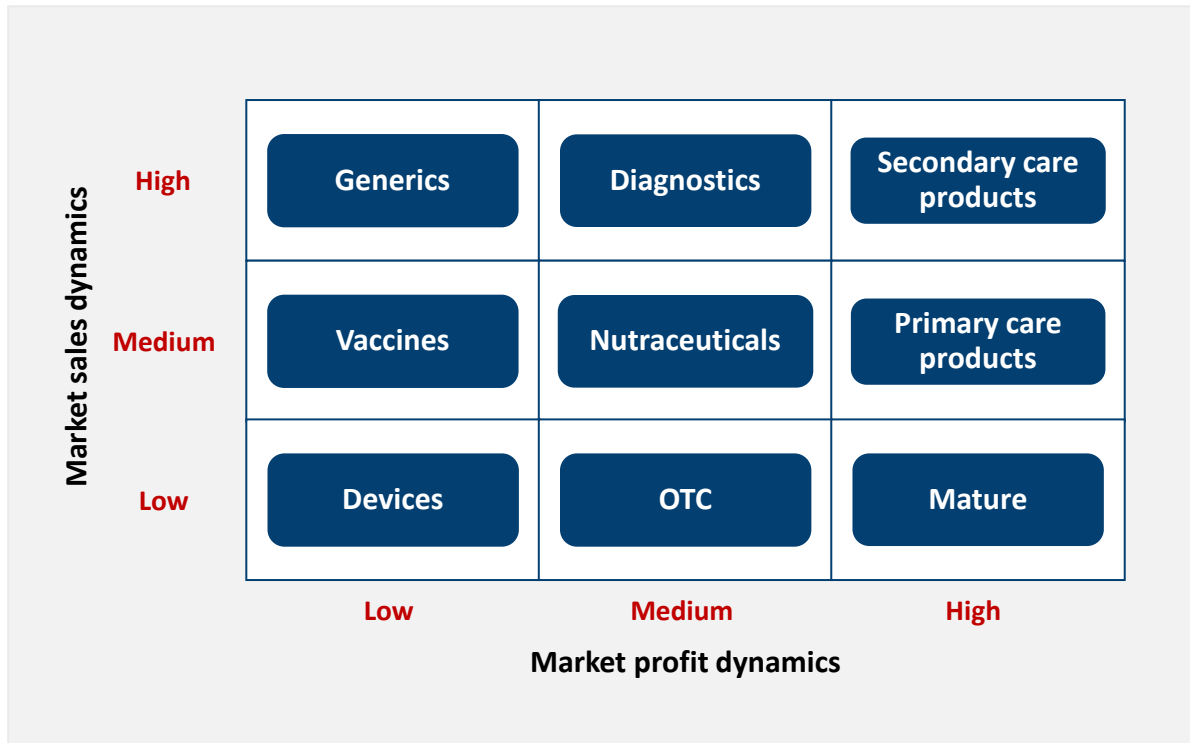
The “5+1 forces framework” is particularly helpful to identify the key stakeholders that will influence the long-term structure and profitability of strategic segments

Business strategy – Attractiveness of strategic segments (2/3)



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

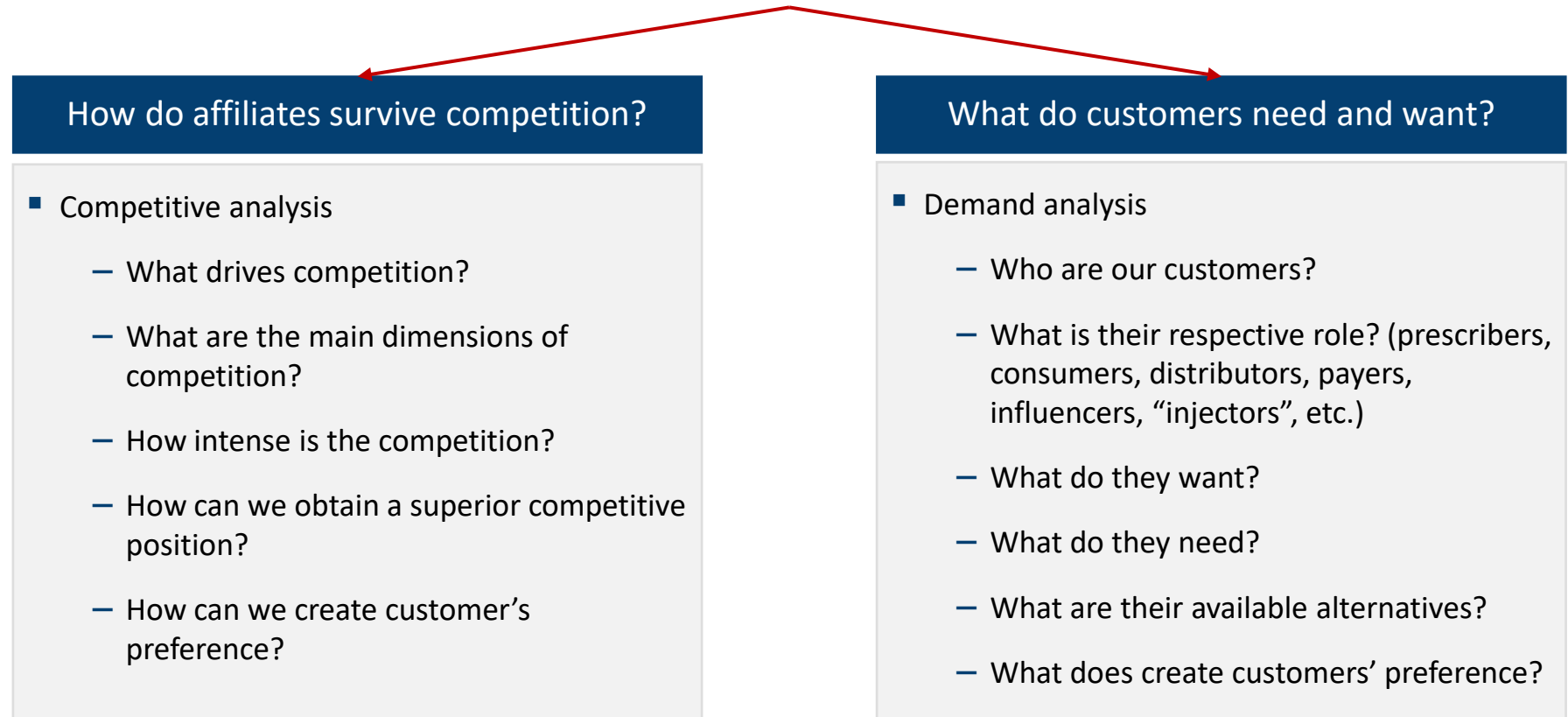
Business strategy – Attractiveness of strategic segments (3/3)



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

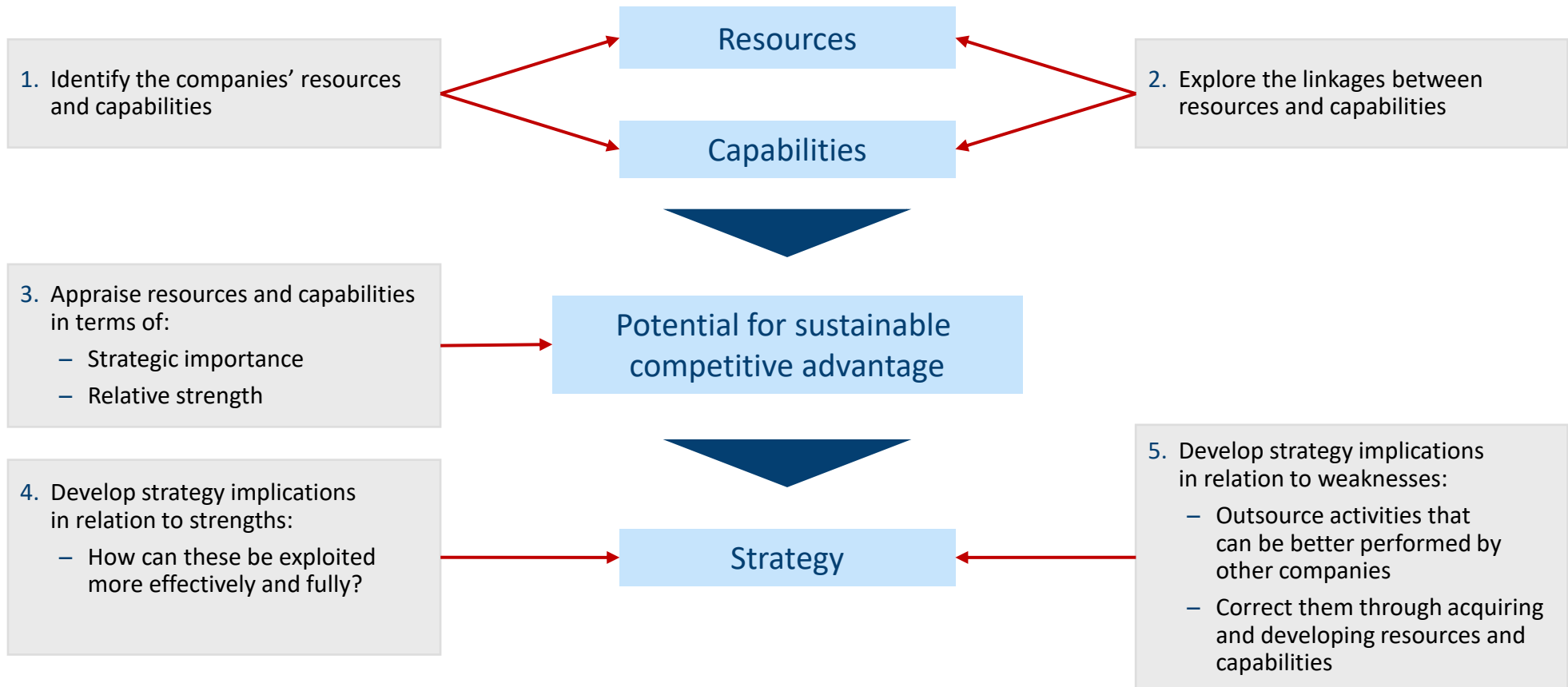
Key success factors by strategic segment where business opportunities have been identified are driven from competitive intensity and from customers needs and wants

Business strategy – Key success factors by strategic segment



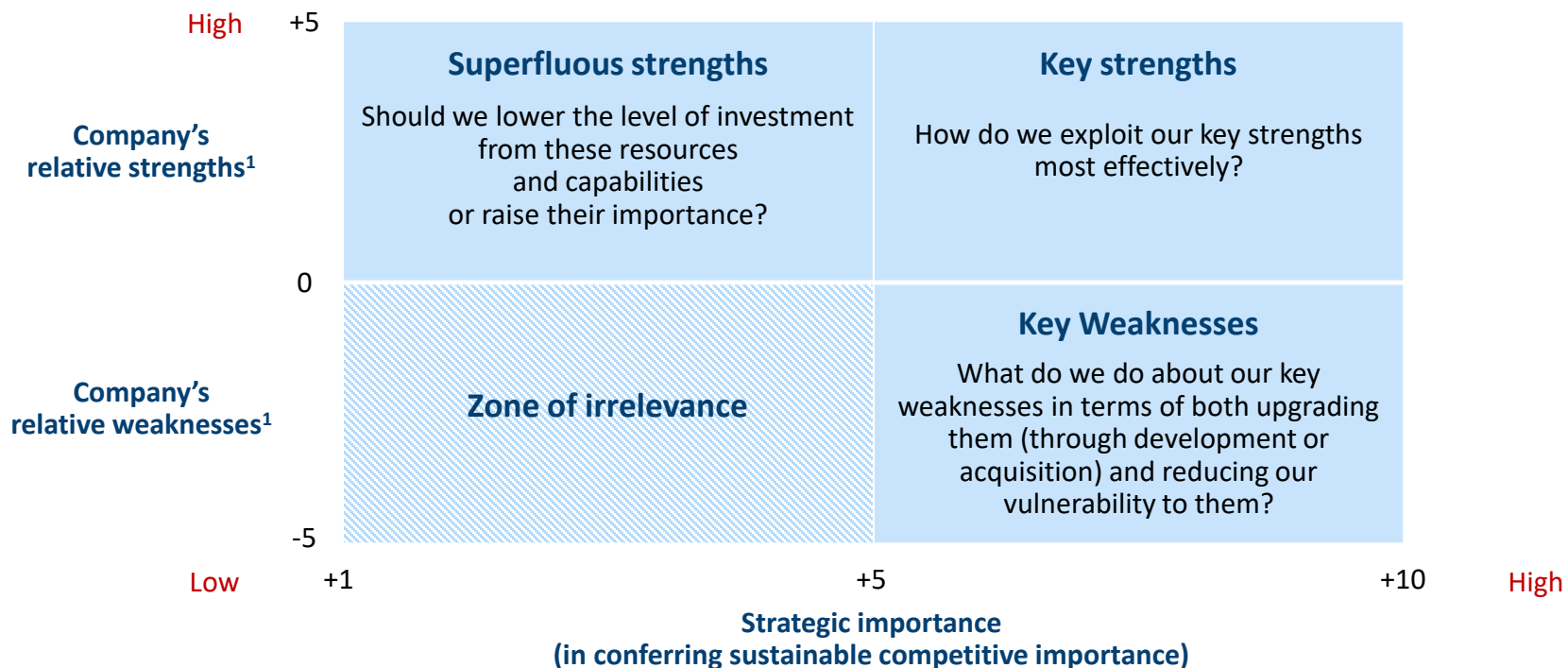
Systematic appraisal of company's resources and capabilities provides the basis for formulating operational strategy

Operational strategy crafting



Pharma companies should reinforce resources and capabilities that are critical to establishing a sustainable competitive advantage to generate superior profits

Operational strategy – Resource and capabilities assessment



“Some resources and capabilities are needed to play, but not needed to win”

Pharma companies' capabilities can be developed or adjusted internally, as well as externally through outsourcing, strategic alliances or merger and acquisition

Operational strategy – Approaches to capability development

Merger & Acquisition

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

Outsourcing

- Companies can access capabilities (and resources) by borrowing them from other companies through outsourcing arrangements

Internal Development

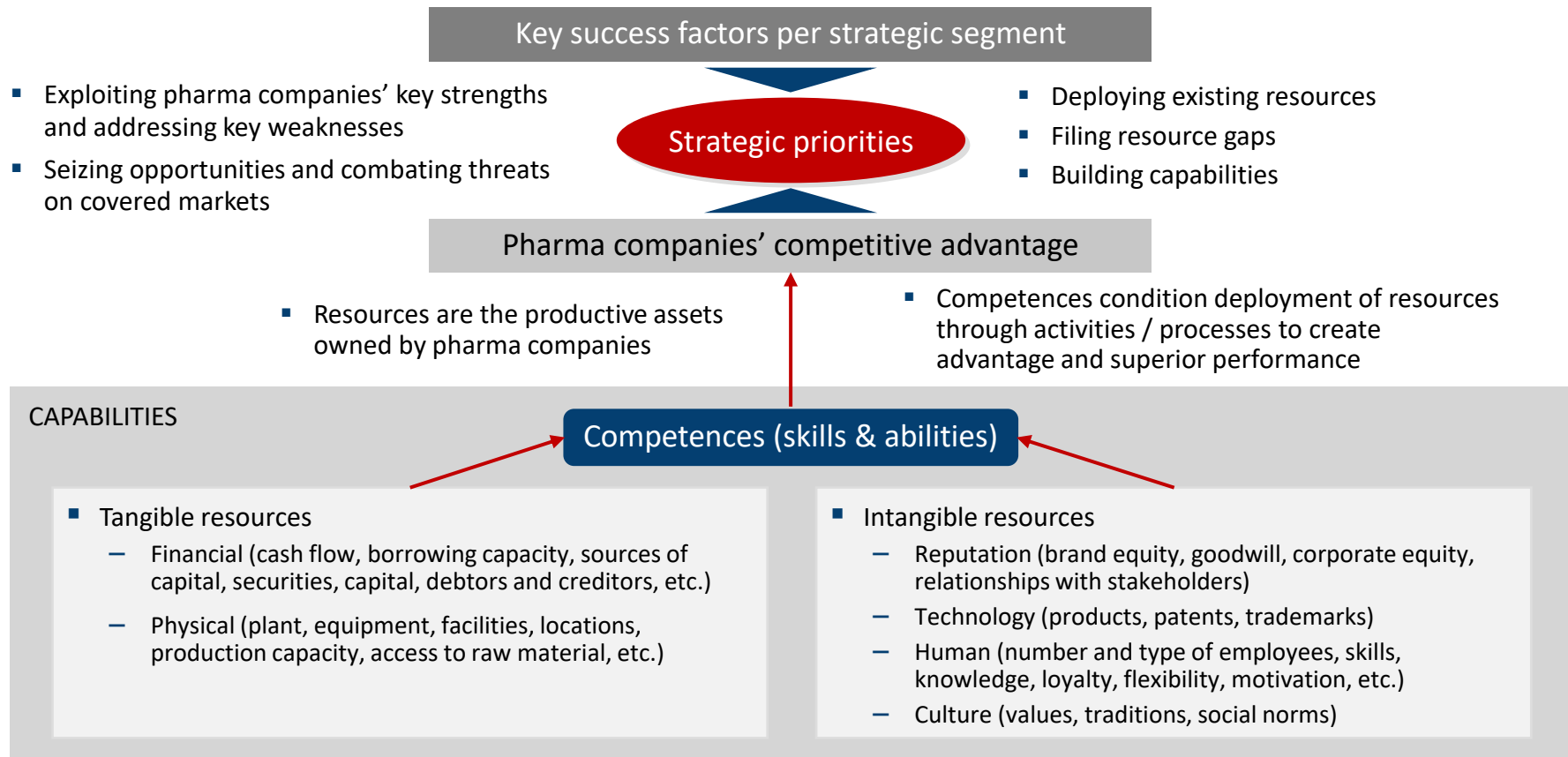
- Growing capabilities requires that companies replicate them internally...
- ... by systematizing the knowledge that underlies capabilities through the formulation of SOPs¹

Strategic Alliances

- Accessing capabilities through alliances offers a more targeted and cost effective mean than acquisition
- A strategic alliance involves the sharing of resources in pursuit of common goals
- Where both alliance partners are trying to acquire one another's capabilities, the result may well be a "competition for competence" that ultimately destabilizes the relationship

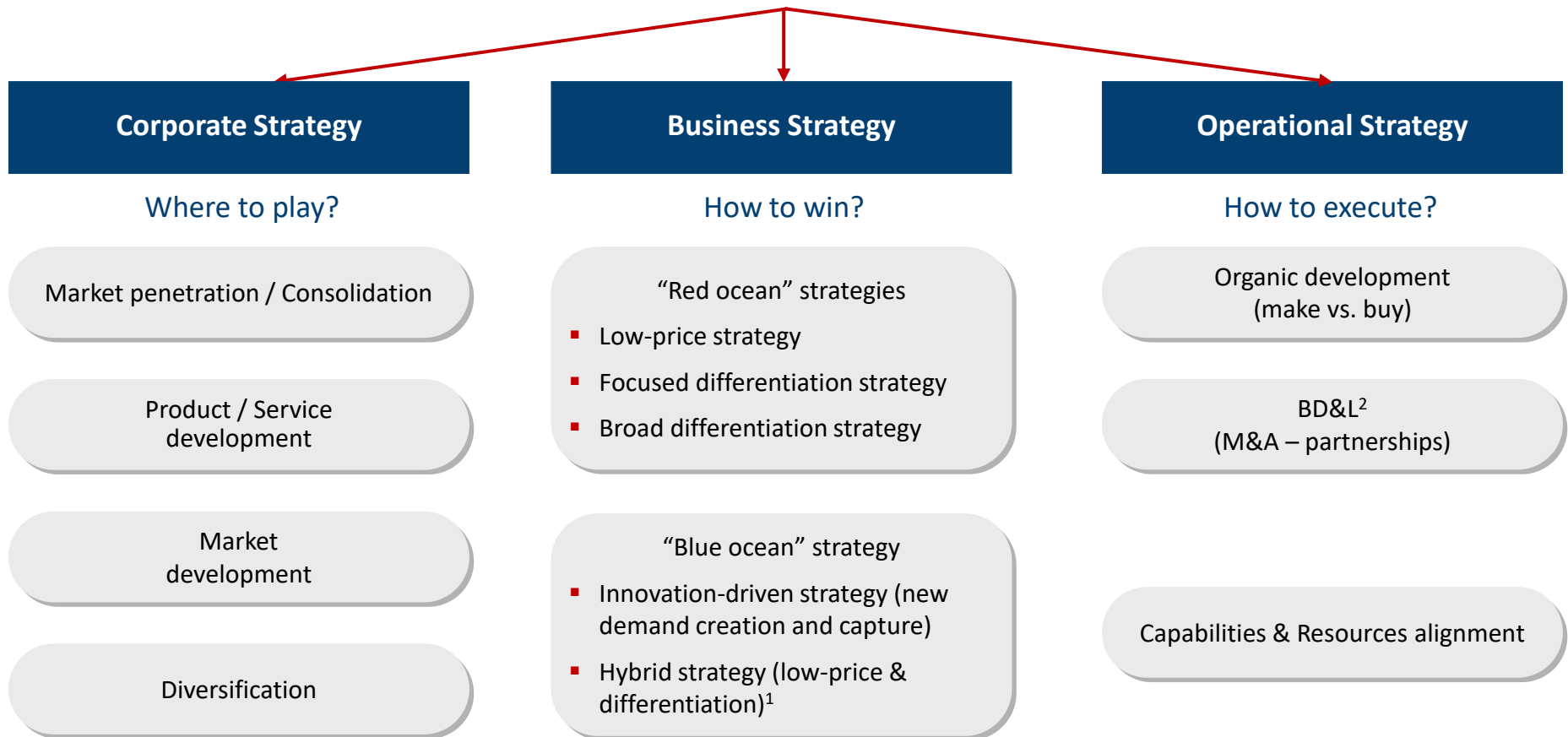
Strategic priorities should be set after capabilities assessment to outperform competitors on key success factors inherent to each targeted strategic segment

Strategic priorities & competitive advantage



The three different strategic levels – corporate, business and operational – must be crafted in a consistent manner to optimize the impact on performance

Multi-level strategic options

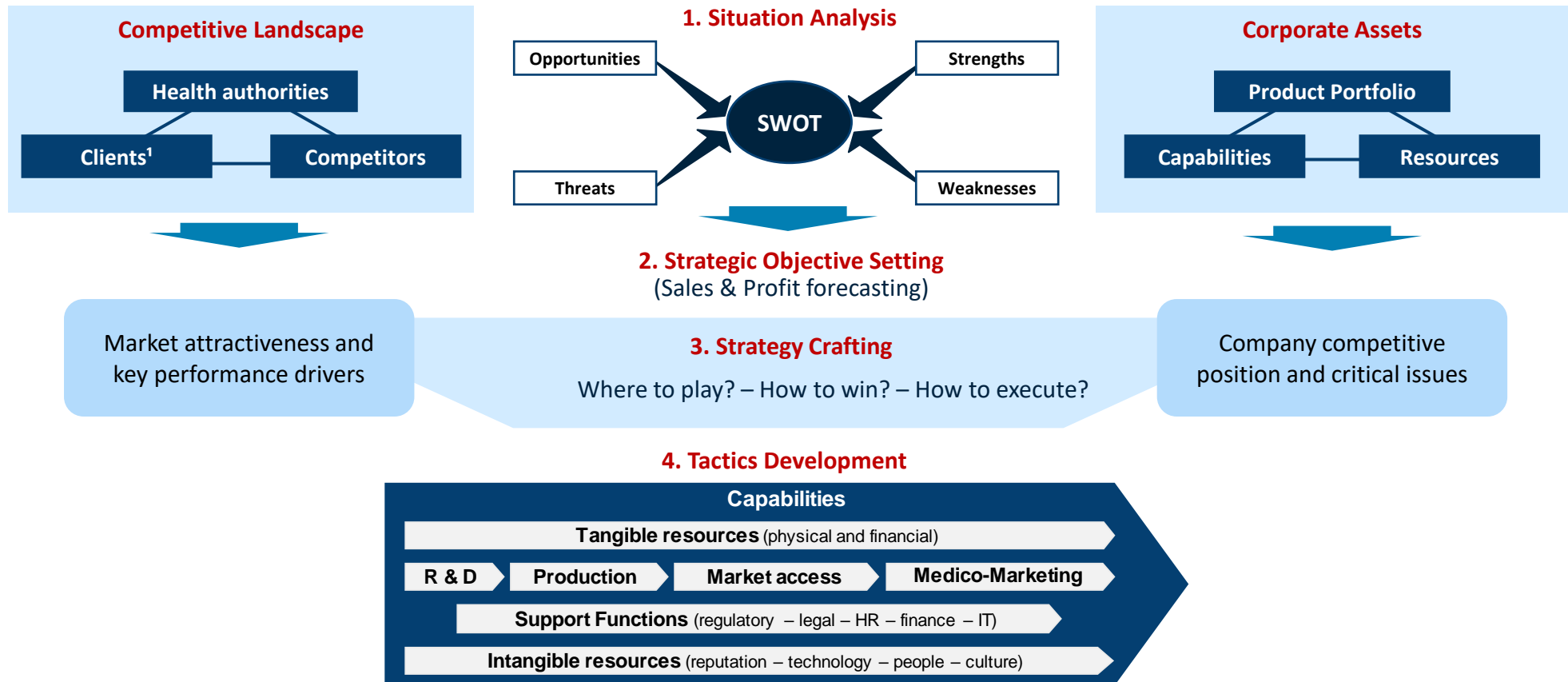


Sources: Adapted by Smart Pharma Consulting from G. Johnson et al., 2008, W.C. Kim & R. Mauborgne, 2005

¹ Eliminating or reducing costs while raising or creating value – ² Business Development & licensing

The strategic thinking process aims at aligning company's unique capabilities and resources to seize market opportunities and address market threats

Strategic thinking framework (1/3)



Smart Pharma Consulting recommends the following approach to craft a strategy at corporate, business and operational levels to boost pharma companies' performance

Strategic thinking framework (2/3)

Situation Analysis

- Kick-off meeting organization
 - Agreement on project management, scope and deliverables
- Historical market and product data analysis (2014 – 2017)
 - Internal and external data collection through desk research, and interviews to acquire the right level of insights
 - Analysis of sales and profits per strategic segment:
 - Competitive landscape (health authorities, clients and competitors' opinions and behaviors)
 - Corporate assets (product portfolio, capabilities and resources)
 - Advanced SWOT analysis
- Sales and profits growth modeling (2018 – 2023) by applying the on-going strategy ("as is" scenario)
- Writing of the situation analysis summary

Strategy Formulation

- Strategy crafting workshops
 - Review of situation analysis outputs
 - Reassessment of the strategic square (purpose, mission, vision, values)
 - Strategic objective setting
 - Review and prioritization of multi-level strategic options (corporate, business, operational)
 - Development of tactics that will support the selected strategies (alignment of capabilities and resources along the different components of the value chain)
- Fine-tuning of the strategy
 - Sales and profits growth modeling (2018 – 2023) following the integration of the recommended strategy and tactics ("boosted" scenario)
 - Final selection of the strategic levers (suitability, efficacy / acceptability and feasibility) to boost the performance
 - Tactical recommendations (key activities supporting strategic priorities) and monitoring tools¹
- Writing of the 2018 – 2023 Strategy Plan

The following enabling tools will help pharma companies make strategic decisions and formalize them in a robust and practical strategic plan

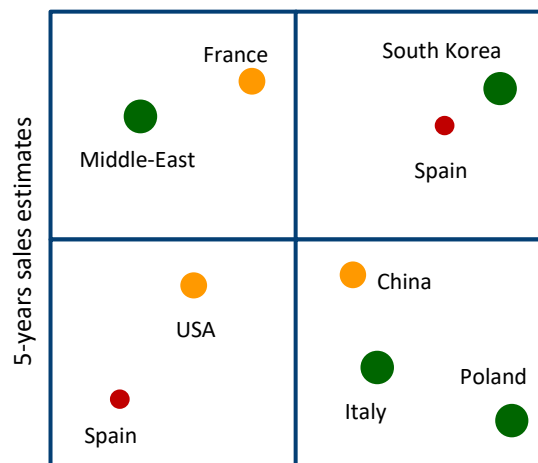
Strategic thinking framework (3/3)

Illustrative

Situation Analysis

Strategy Formulation

Potential of current strategic segments by country

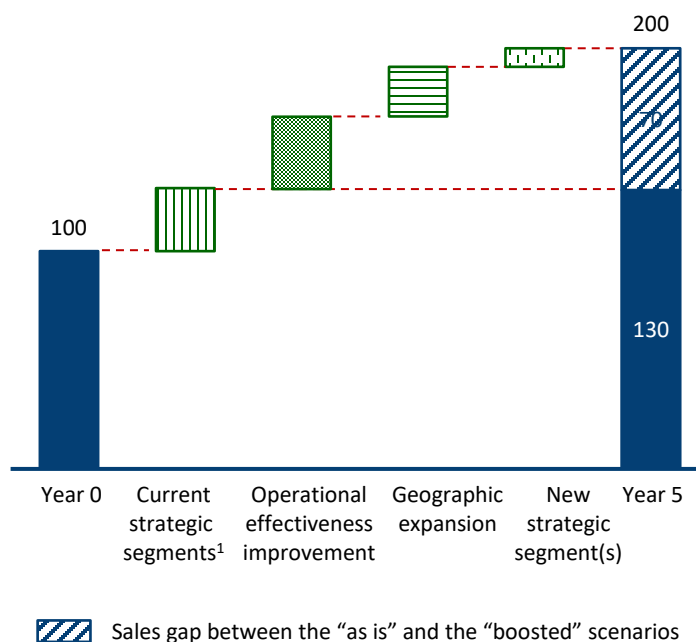


5-year profits estimates

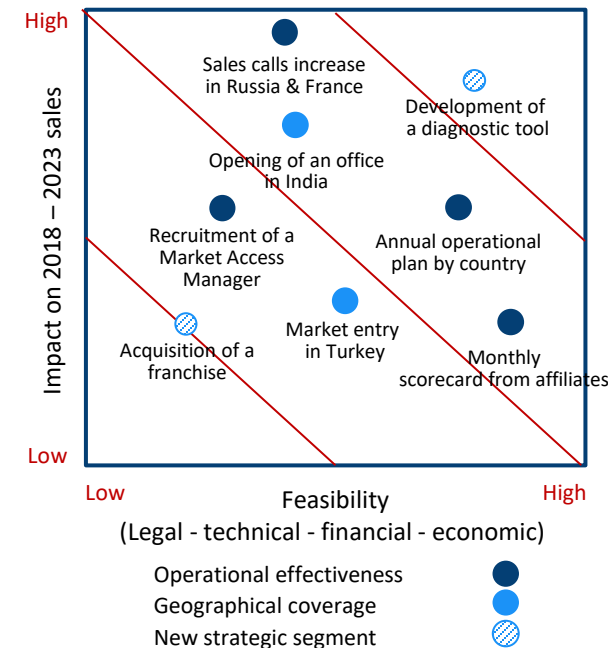
Operational effectiveness level

Low ● Moderate ● High ●

5-year sales growth estimates



Prioritized strategic levers



This masterclass has been designed to help pharma executives build robust and relevant strategies while ensuring their proper execution for an optimal result

Masterclass: Pharma Strategy & Operational Excellence

Day 1: Market Analysis

- 9:00 Introduction to the masterclass
- 9:10 Review and discussion of most appropriate concepts, methods and tools to analyze current strategies (at corporate, business and operational levels)
- 10:30 *Break*
- 10:45 Case study #1: **Strategic situation analysis:**
 - Analysis of strategic segments covered
 - Analysis of products/services offered by segment
 - Corporate, business and operational strategy assessment
- 13:00 *Lunch*
- 14:00 Presentation of the case study outputs, discussion and agreement on key learnings
- 15:30 *Break*
- 15:45 Lecture by and discussion with an expert:
“Review of the most audacious and successful strategies – Lessons from non pharma markets”
- 17:00 End of the 1st day

Day 2: Strategy Crafting & Execution

- 9:00 Introduction to the 2nd day
- 9:10 Review and discussion of most appropriate concepts, methods and tools to craft and execute strategies (at corporate, business and operational levels)
- 10:30 *Break*
- 10:45 Case study #2: **Strategy crafting:**
 - Setting a strategic objective
 - Selecting strategic options at corporate, business and operational levels
- 13:00 *Lunch*
- 14:00 Presentation of the case study outputs, discussion and agreement on key learnings
- 15:00 Case study #3: **Strategy execution:**
 - Developing high execution standards
 - Monitoring the quality of execution with KEIs¹
- 16:15 *Break*
- 16:30 Presentation of the case study outputs, discussion and agreement on key learnings
- 17:30 End of the masterclass

Pharma Strategy at Affiliate Level

BEST-IN-CLASS SERIES

A practical guide

“Uncertainty created by the Covid-19 crisis, requires – more than ever – to conduct a robust strategic thinking”

This document proposes a methodology and tools to help management committees of Pharma companies' affiliates craft a robust strategy, despite the high uncertainty due to the Covid-19 crisis

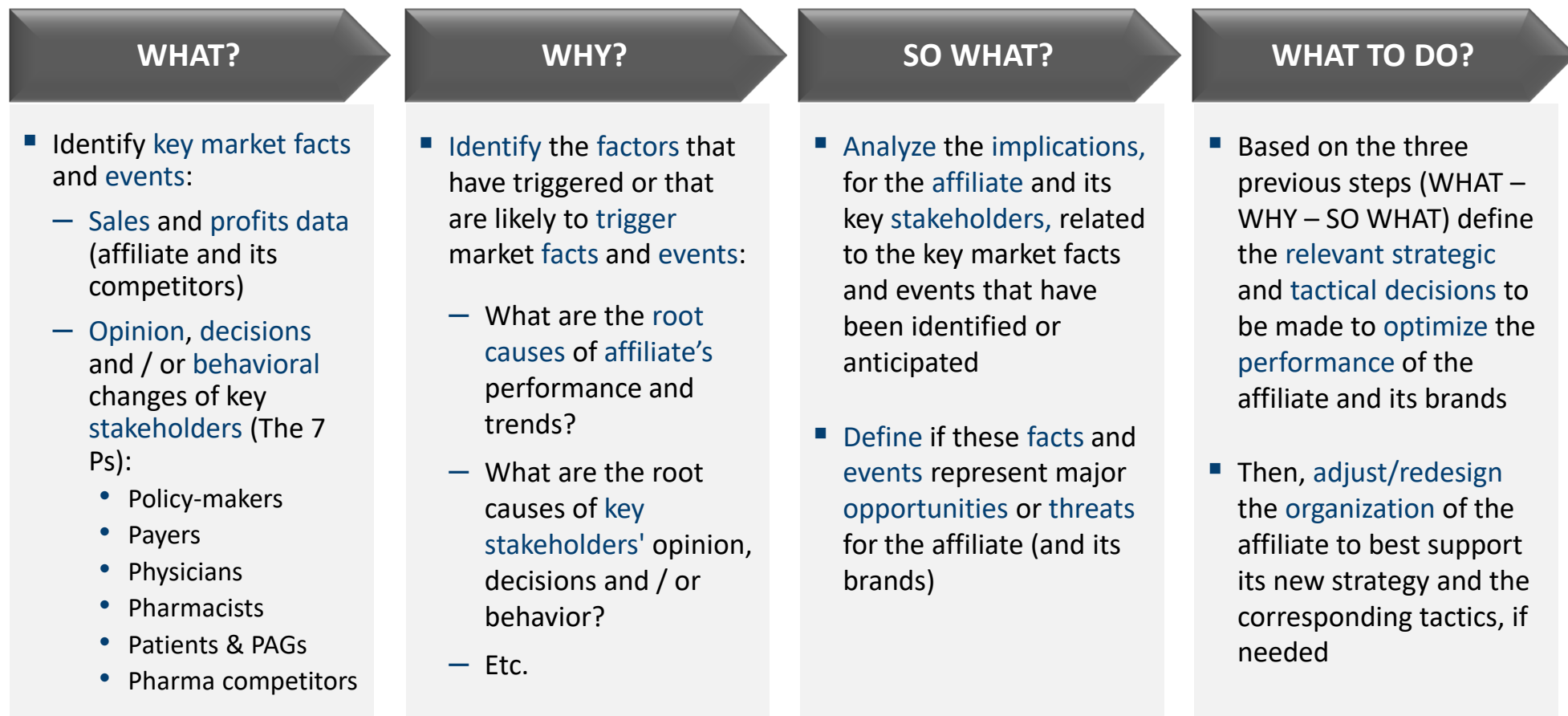
Introduction

- An unprecedented crisis triggered by the Covid-19 pandemics has hit the world since early 2020
- All kinds of specialists¹ have emerged to the public, explaining what is going to happen and what should have been done to better manage the crisis
- The problem is that all those thought leaders have been very poor at predicting the future...
- ... and quick at making sweeping recommendations, based on hasty and shallow thoughts
- At Smart Pharma Consulting we do think that, more than ever, pharma companies' Affiliates and their management committee should:
 - Carry out a robust analysis of the 2019-2020 period
 - Build scenarios for the 2021-2025 period, based on documented assumptions and a formal processto better seize opportunities and address threats while leveraging with a greater efficacy the company's assets
- For so doing, we propose the “Smart Strategic Model” proven methodology, tools and a customized support

“The Covid-19 crisis has discredited a bunch of arrogant forecasters and lazy trouble shooters, reinforcing the value of a formal strategic thinking process”

The 4 Ws approach that we have developed enables Affiliates to make evidence-based strategic, tactical and organizational decisions and thus improve their relevance and consistency

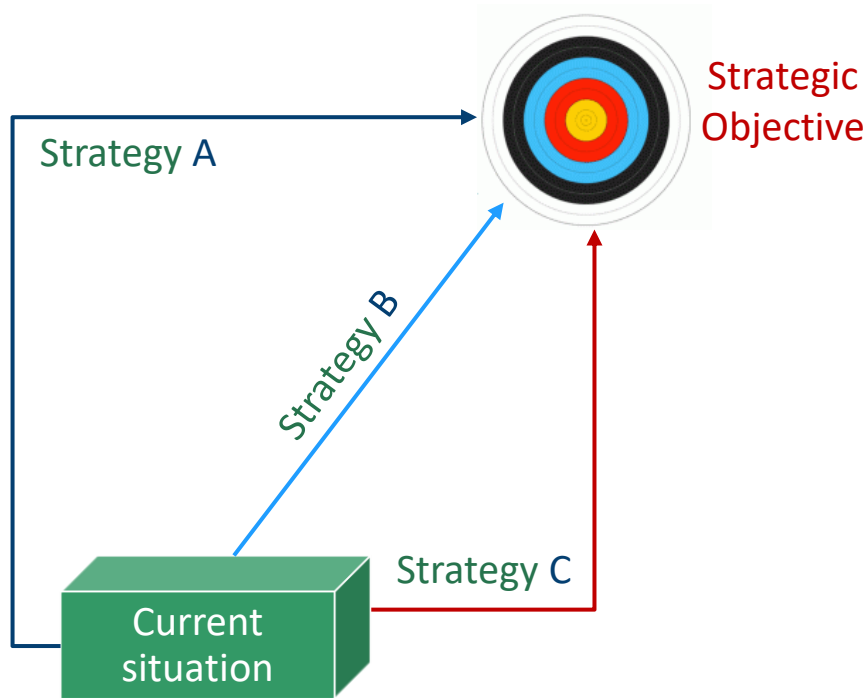
The 4 Ws approach



The 4 Ws approach that we have developed enables Affiliates to make evidence-based strategic, tactical and organizational decisions and thus improve their relevance and consistency

The Smart Strategic Model – Principle

- Strategies at affiliate's level should be considered in a time horizon of 3 to 5 years
- To achieve an objective, different strategies may be considered



- Affiliate's strategy will be based on criteria such as:
 - Constraints (e.g., legal, technical or financial constraints, deadlines, corporate decisions, market threats, competitive weaknesses)
 - Drivers (e.g., capabilities, specific know-hows, market opportunities, competitive advantages)
 - Habits (e.g., willingness to remain or step out of the Affiliate's comfort zone)
- The likelihood to achieve the set objective depends as much on the selected strategy as on supporting activities (tactics) and the excellence in their execution

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

The Smart Strategic Model – Principle



- **Vision:** What do we aspire to become?
- **Mission:** What do we do and for whom?
- **Values:** What do we believe in and how do we behave?

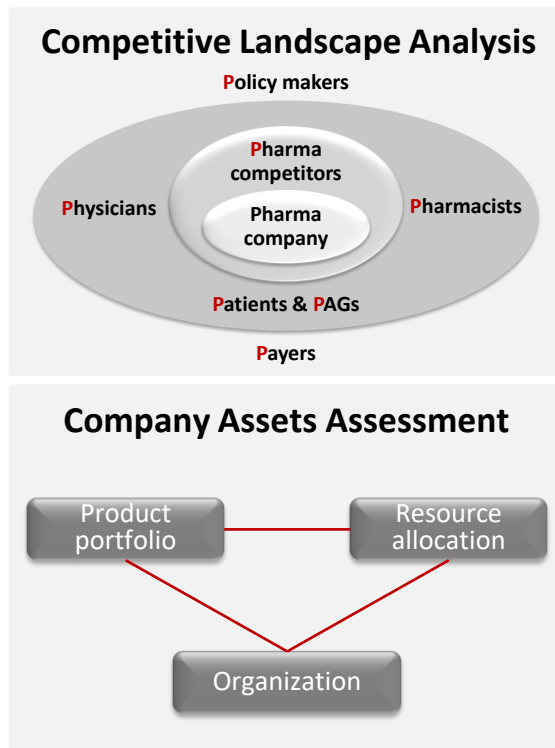
- **Objective:** What do we want to achieve?
- **Strategy:** Where to play and how to win?
- **Tactics:** How to execute the strategy?
- **Organization:** What activities, processes, structure¹ and culture we put in place to execute the strategy?

- **Expected Outcomes:**
 - Are they in line with the strategic triangle?
 - Are they consistent with the set objectives?
 - How are they going to be monitored?

The strategy should be crafted based on a robust analysis of the situation and its trends, and the strategic objective set, prior to the design/adjustment of the organization

The Smart Strategic Model – Principle

1. Situation & Trends Analysis



2. Strategic Objective

3. Strategy Crafting & Tactics



4. Organization Design



The competitive landscape analysis consists in identifying the current and evolving opinions and behaviors of key stakeholders, the corresponding driving factors and the implications for Affiliates

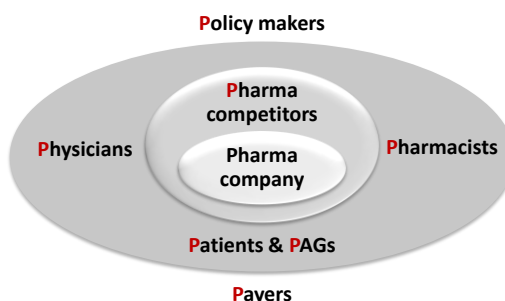
The Smart Strategic Model – 1. Situation & Trends Analysis

Illustrative

Competitive Landscape Analysis

Policy makers / Payers

- Registration process and policies
- Pricing and reimbursement policies
- Medical guidelines developed by health authorities
- Trade regulations
- Public health initiatives



Pharma Competitors

- Customer preference strategy:
 - Product portfolio
 - Service offering
 - Corporate reputation
- Resource allocation (medico-marketing & sales)
- Organizational model

Physicians

- Evolving practice (working time and organization, tele-medicine)
- Prescribing habits and alignment with guidelines
- Budget constraints
- Relationships with patients
- Relationships with pharma companies (in-field and office-based collaborators)
- Unmet needs

Patients / PAGs

- Role of PAGs to influence other stakeholders (e.g., authorities, physicians, individual patients)
- Position vis-a-vis pharma companies
- Relationships with HCPs
- Patients' knowledge re. health and pharma ecosystem
- Unmet needs

Pharmacists (hospital-based)

- Drug listing and purchasing policy
- Position re. the use of generics and biosimilars
- Power of influence within the hospital

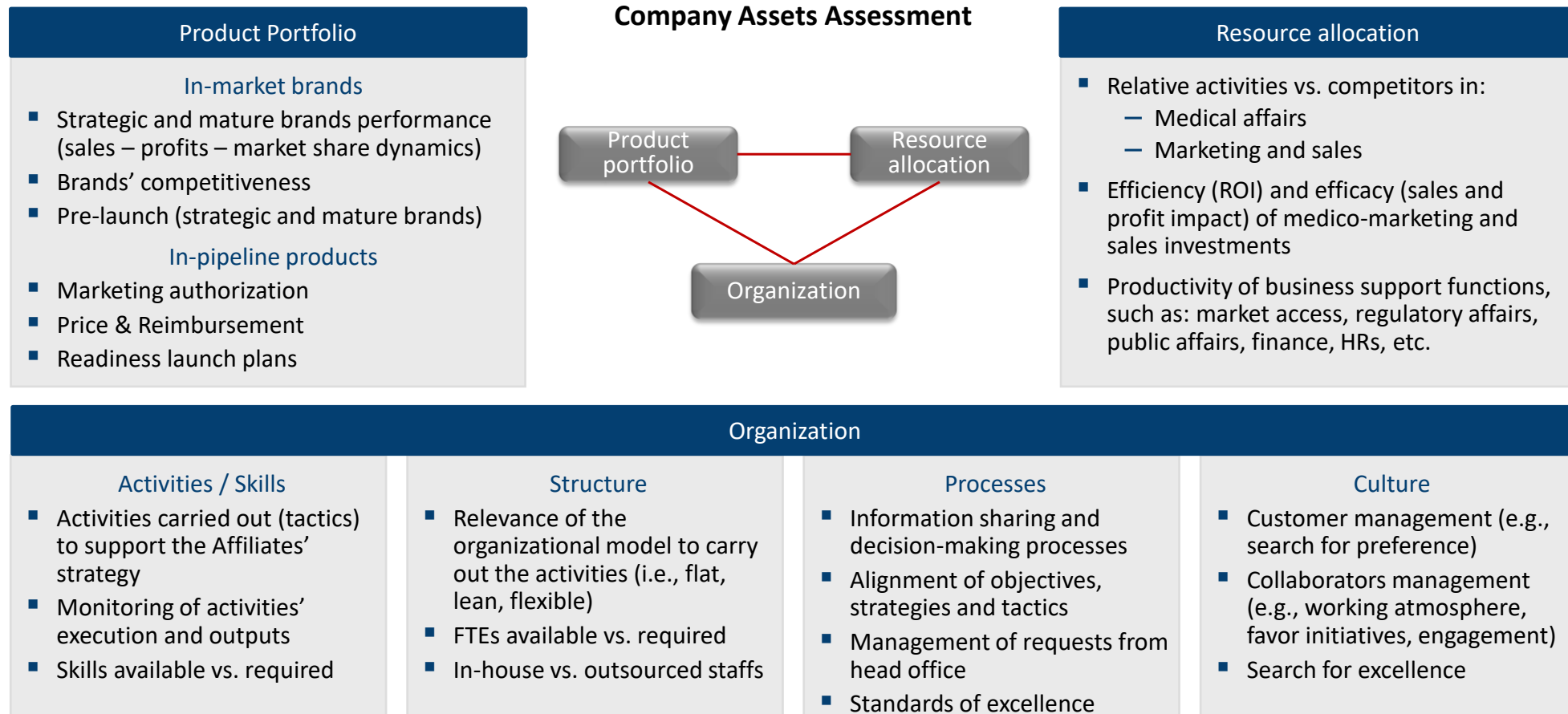
Pharmacists (retailers)

- Role in public health initiatives (e.g., screening, education at the point of sale)
- Purchasing policies and selling priorities

The affiliates should evaluate their assets by reviewing their competitive position about their product portfolio, their available resources and the configuration of their organization

The Smart Strategic Model – 1. Situation & Trends Analysis

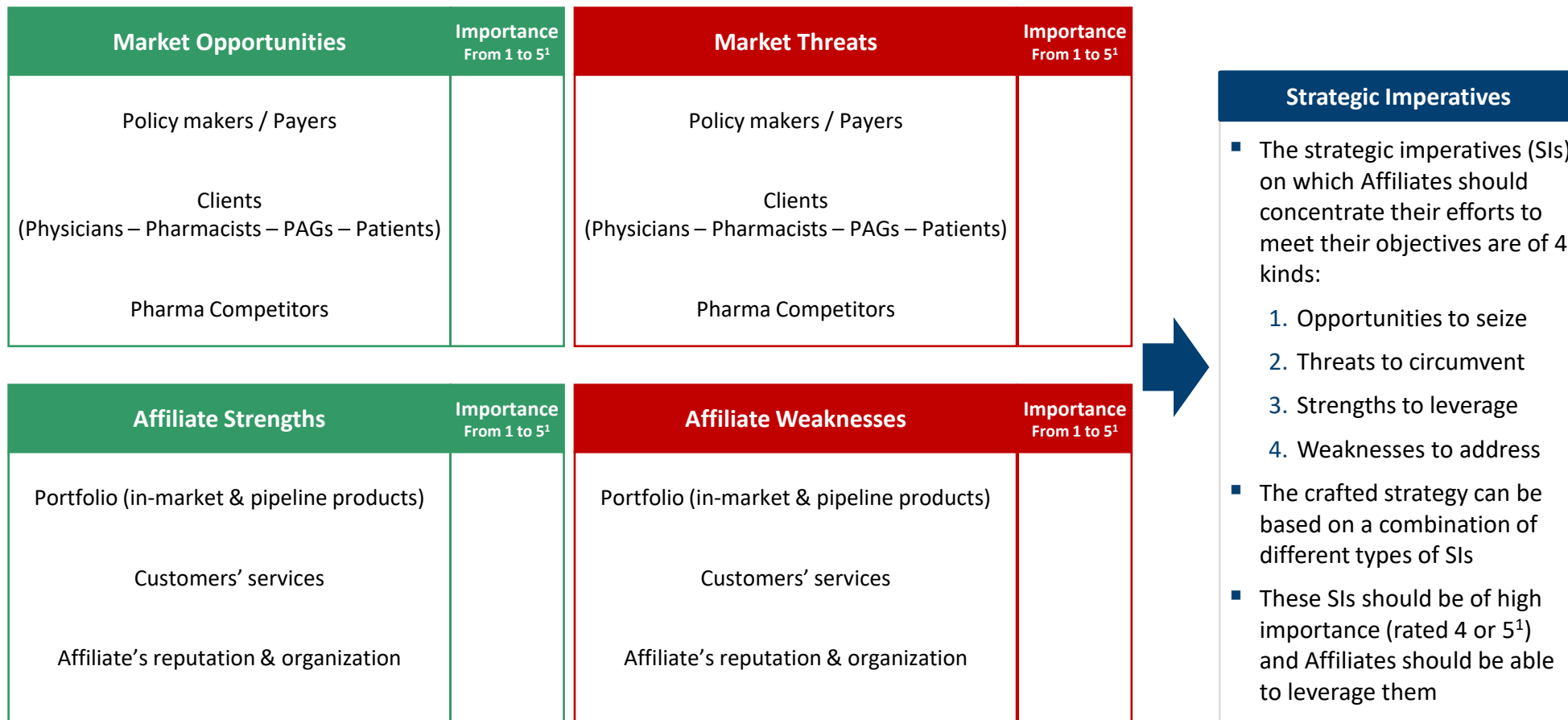
Illustrative



The “Advanced SWOT” facilitates the identification of strategic imperatives which are opportunities to seize, threats to circumvent, strengths to leverage and/or weaknesses to address

The Smart Strategic Model – 2. Advanced SWOT & Strategic Imperatives

Illustrative



The affiliate's strategic card which must be developed by the management committee enables to represent on the same page the strategic objective, the strategic imperatives and the key tactics

The Smart Strategic Model – 3. Strategic card design - Department level

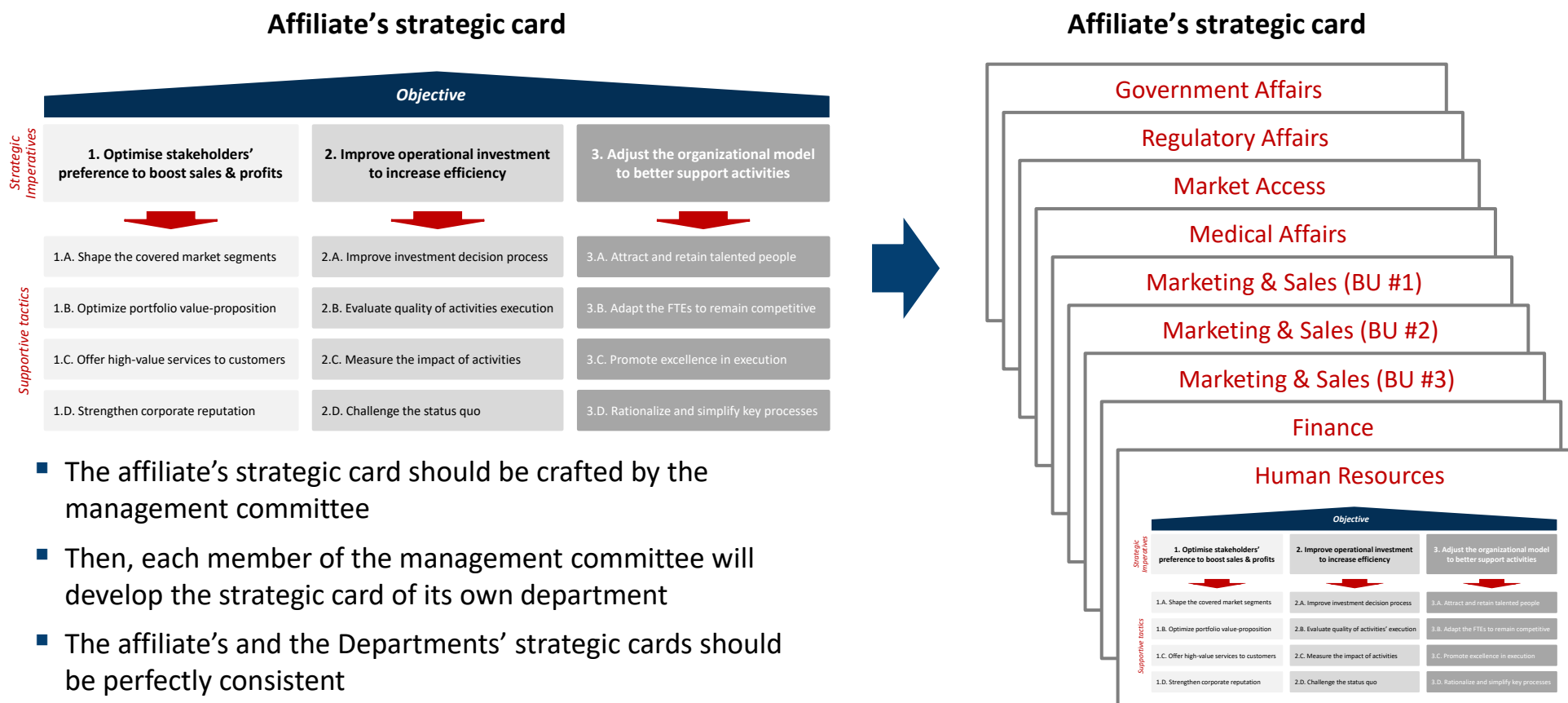
Illustrative



The affiliate's strategic card will then be translated at each department level by each member of the management committee who will ensure the perfect consistency between the two levels

The Smart Strategic Model – 3. Strategic card design - Department level

Illustrative



This model of ID card will help management committee members plan and monitor the execution of the key activities that have been selected to support the selected strategic imperatives

The Smart Strategic Model – 4. ID card design by key tactic

Illustrative

- SI: precise the SI this tactic is supposed to support
- Objective: define the specific objective of this tactic
- Description: describe briefly the tactic

- Stakeholder type: internal, external (e.g., authorities, payers, HCPs, PAGS)
- Number of stakeholders:

Priority
One – Two

Planning	Actions			Timing	Owner	FTEs	OPEX
Key actions to implement this tactic							
Monitoring	Quantitative / qualitative metrics	Indicator objective	Indicator achievement		Key implications / Comments		
Key Execution Indicators (KEIs) ¹ (quality of execution)							
Key Performance Indicators (KPIs) ¹ (Impact of the action)							

Smart Pharma Consulting can help Pharma affiliates develop a practical and consistent Strategic Plan, along with a series of tools to monitor the excellence of its execution

Key takeaways & Smart Pharma Consulting Support

- The “Smart Strategic Model” is straightforward to implement by affiliates, irrespective of their size
- The 1st step consists in developing robust and well-structured market insights as illustrated by the report we have just published for the French Pharma market¹
- During the 2nd step, the management committee of the Affiliate will develop an “Advanced SWOT” from which strategic imperatives will be drawn
- The 3rd step focuses on aligning on one page:
 - The Affiliate 3- to 5-year objective
 - The corresponding strategic imperatives (SIs)
 - The supportive tactics
- Then, the management committee members will develop the Strategic Card of their department...
- ... and will plan and monitor their key activities with the help of a “Key Activity ID Cards”



Smart Pharma Consulting has a long experience in supporting Affiliates – of any size – to develop a robust, consistent and relevant Strategic Plan with the help of a simple and proven methodology, and easy-to-use tools

How to Boost Corporate Reputation?

————— BEST-IN-CLASS SERIES —————

A practical guide for
pharma companies

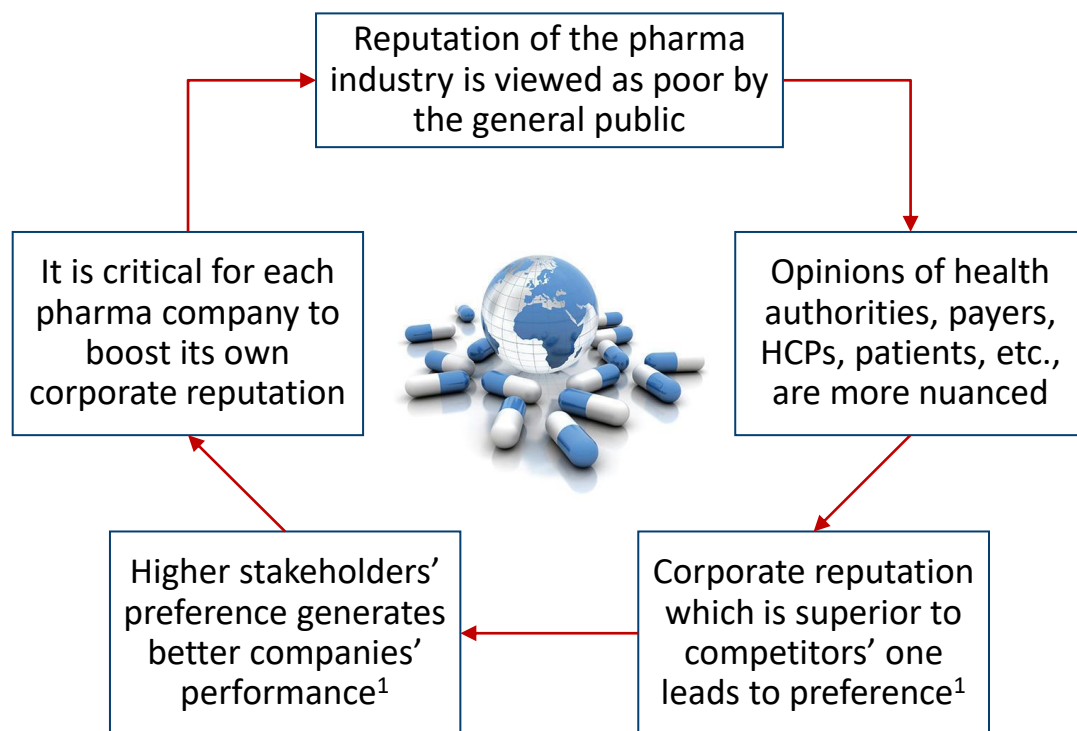
*“A strong reputation is associated with
trust and esteem, generating
stakeholders’ preference”*

This position paper analyzes the corporate reputation of the pharma industry and proposes The Pharma Reputation Booster™ approach to help affiliates improve their performance

Introduction

Corporation reputation situation & solutions

Pharma industry situation



Solutions for affiliates at national level

To enhanced their corporate reputation, at national level, affiliates can implement the Pharma Reputation Booster™ approach designed by Smart Pharma Consulting:

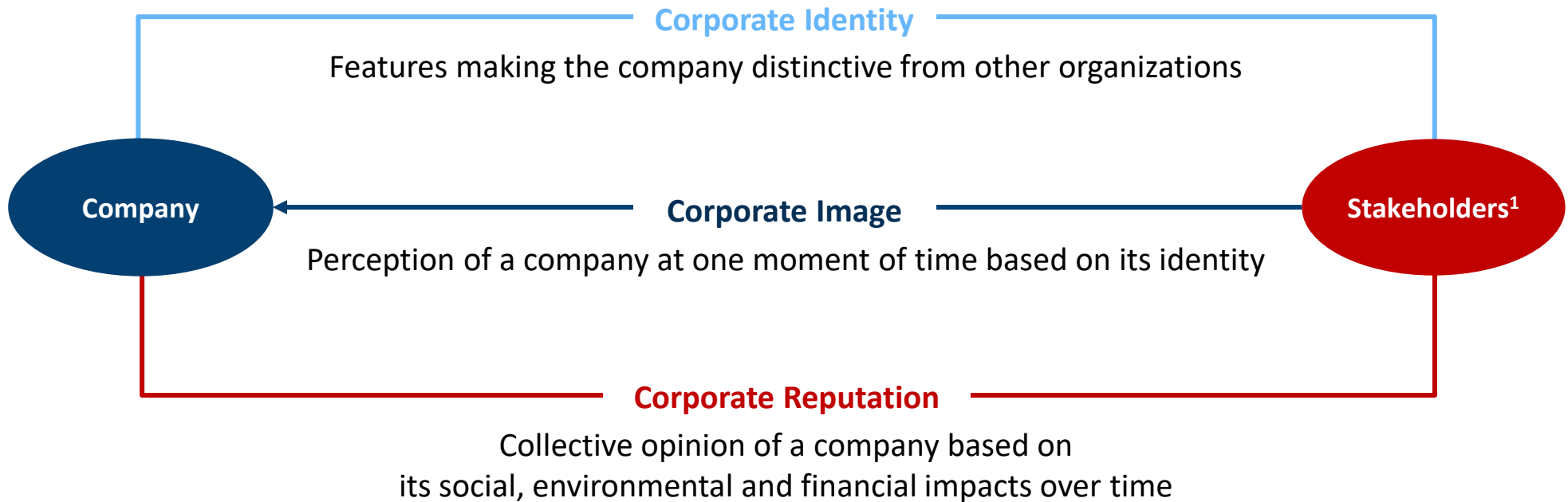
- Phase 1**
 - Analyze and map the key stakeholders
 - Measure affiliates' reputation with the "Pharma Reputation Index"
- Phase #2**
 - Select the key drivers to pharma companies' reputation by stakeholder
 - Develop an action plan and monitoring tools
- Step #3**
 - Make the reputation a priority for employees
 - Adjust the organization, whenever required
 - Design a Pharma Reputation Scorecard

"Reputation and trust are earned through actions, results, and communication to stakeholders"

Corporate reputation depends on what the company does,
the way it does it, and the results of its actions

Introduction

Link between corporate Identity – Image – Reputation

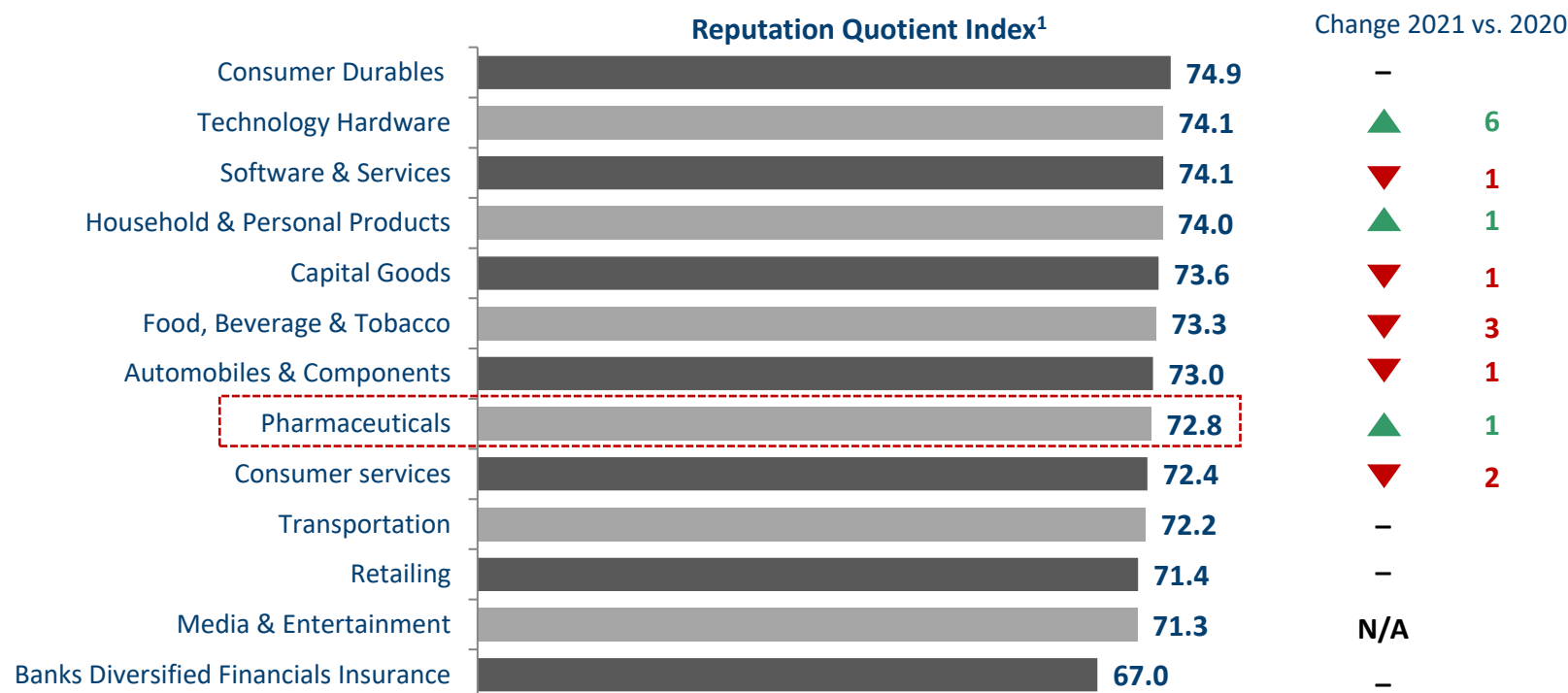


“It takes 20 years to build a reputation and five minutes to ruin it” W. Buffet

If the pharma industry's role to fight the Covid-19 pandemic has contributed to improve its reputation, it is still behind consumer goods and tobacco, for reasons that are mainly structural

Situation analysis & Key learnings

Corporate reputation ranking by sector (2021)



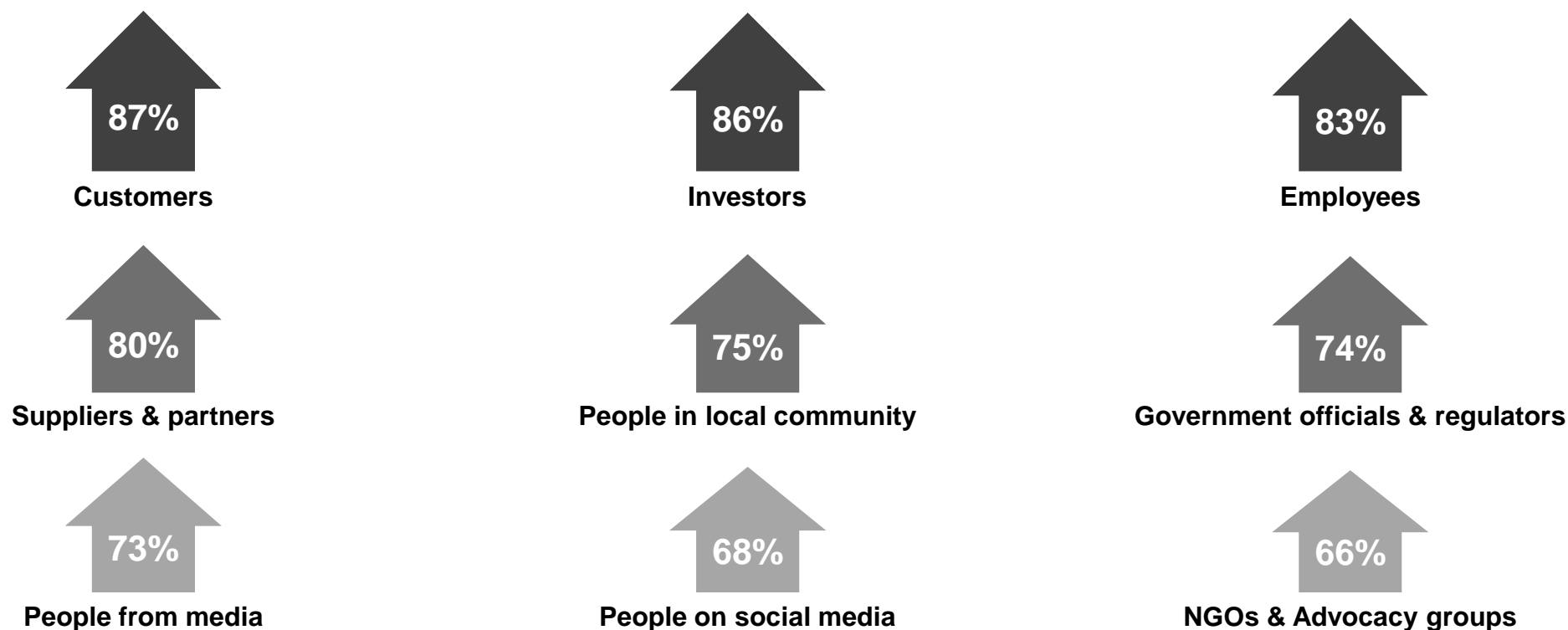
“Distrust of pharma companies stems from a belief that they have deviated from their mission of improving public health to focus on increasing profits”

If all stakeholders are important, some appear to have a greater influence on corporate reputation and should therefore benefit from a special attention

Situation analysis & Key learnings

Importance of various stakeholders on corporate reputation (2020)

% of very / somewhat important impact¹



Sources: Adapted from Weber Shandwick & KRC Research study (2020) by Smart Pharma Consulting

¹ Based on an online survey conducted among 2,227 executives from 22 countries and a variety of industries around the world

A good corporate reputation contributes to improve operational efficacy and efficiency which impacts companies' performance

Situation analysis & Key learnings

Impact of good corporate reputation on companies

Generate **more positive feedback** from media and pressure groups

Drive **profitable sales** in crowded markets

Attract, motivate and retain **talented employees**



Encourage consumers to buy products and services

Enable to better resist to crises and recover faster

Attract **capital resources** and strategic business partners

Lead to greater support from **policy makers, regulators** and rating agencies

Irrespective of the sector, corporate reputation depends on multiple factors which requires to implement a multi-directional strategy to enhance the current situation

Situation analysis & Key learnings

Corporate reputation drivers – Executives' view (2020)

% of executives having rated ≥ 8 on a 10-point scale¹



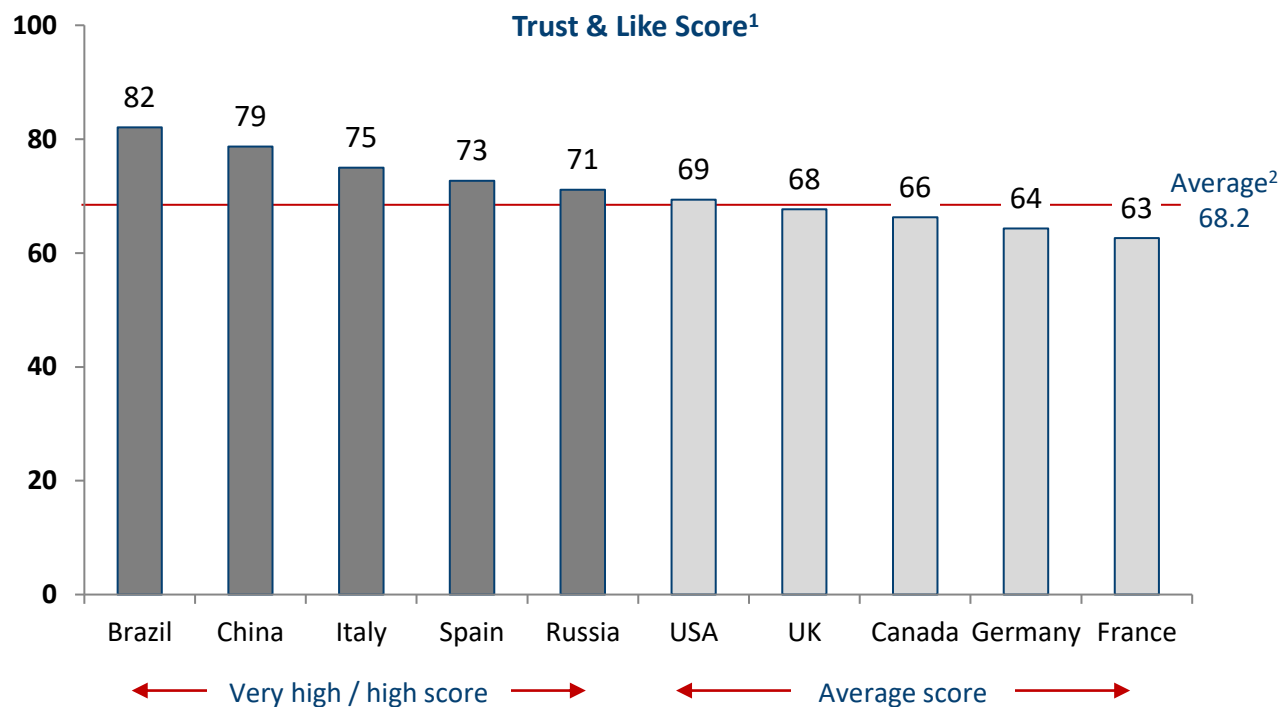
Most important components

- How the company responds to and addresses crises, issues
- Ability to communicate and deliver upon its mission, vision and values
- Communication to the public
- Communication to employees
- Awards or ranking on “best of” lists
- Communication and interactions on social media
- Participation of company’s leaders to business forums, conferences, etc.
- Presence of company’s leaders on the corporate website and social media

The reputation of the pharma industry varies by country and appears to be inversely proportionate to the perceived quality of the healthcare system and of the national wealth

Situation analysis & Key learnings

Pharmaceutical industry reputation by country (2020)



- The pharma sector is perceived differently by the general public according to the countries
- Perceptions and expectations are impacted by the local context, the social, economic and political environment
- The overall reputation of pharma companies appears to be higher in emerging and Southern European countries than they are in Northern European ones and the USA
- Analyses carried out by the Caliber Group show that the lower the perceived quality of the healthcare system, the higher the pharma companies' reputation
- There is also an inverse correlation between GDP per capita and perception of pharma companies
- In wealthier countries, with better healthcare system, citizen are less informed about pharma companies' offering which are relatively less valued

Assessment of individual pharma companies' reputation by general public can vary significantly according to the study carried out and thus, should be viewed as an indicative information

Situation analysis & Key learnings

Big Pharma companies' reputation ranking by general public

Reputation Quotient Index (2021)



- The 2021 Global RepTrak 100, published by The RepTrack Company is based on data collected:
 - Across the 15 largest economies in the world
 - From 68,577 respondents through online surveys
 ... and on 7 indicators: Products/Services – Innovation – Workplace – Governance – Citizenship – Leadership – Financial performance
- Amongst the top 100 most reputable companies that have been assessed, only five belong to the pharma industry
- The study evidenced that the general public is not familiar with pharma companies and thus cannot make an informed opinion

Trust & Like Score¹ (2020)

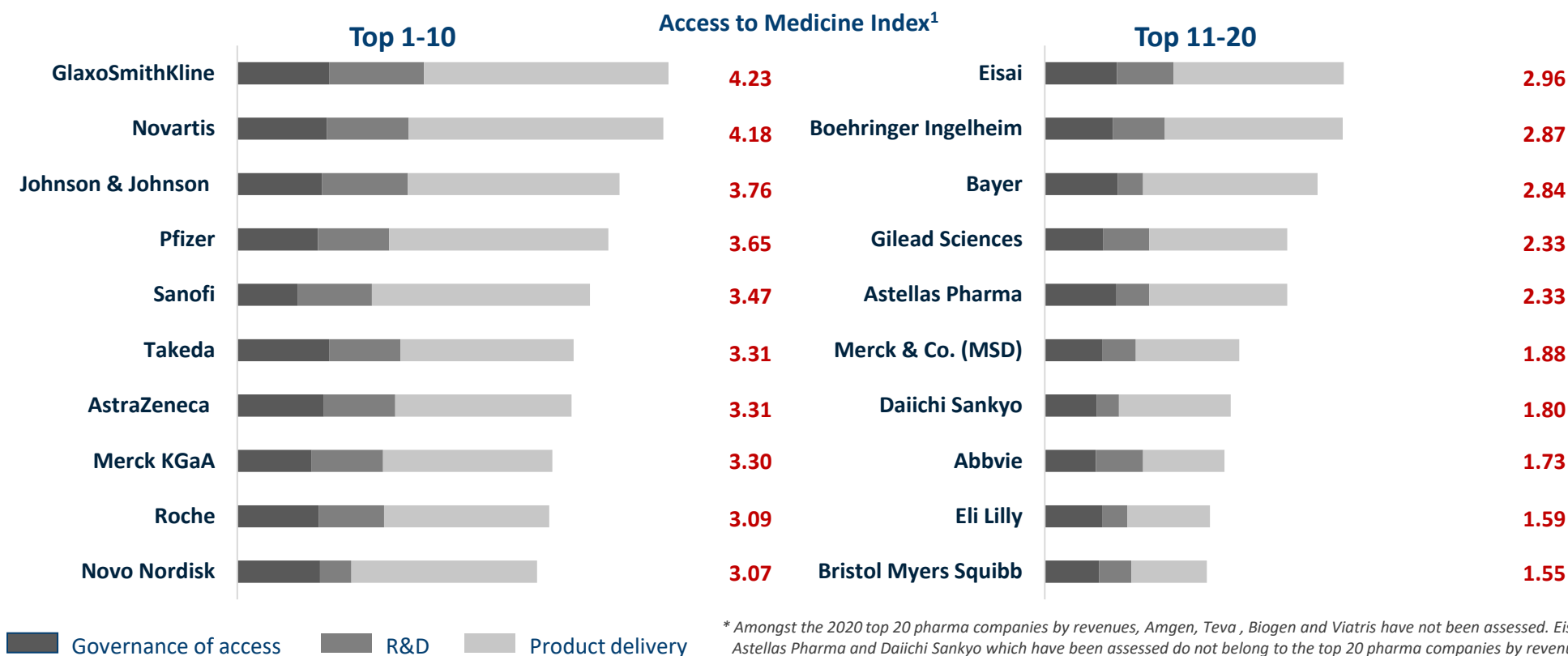


19 of the top 20 pharma companies by revenues in 2020 have been ranked by Caliber according to its "Trust & Like Score" methodology (Viatris having not been assessed)

The Access to Medicine Index which evaluates the biggest pharma companies re. access strategies and practices, provides directions to better address the specific needs of low-income countries

Situation analysis & Key learnings

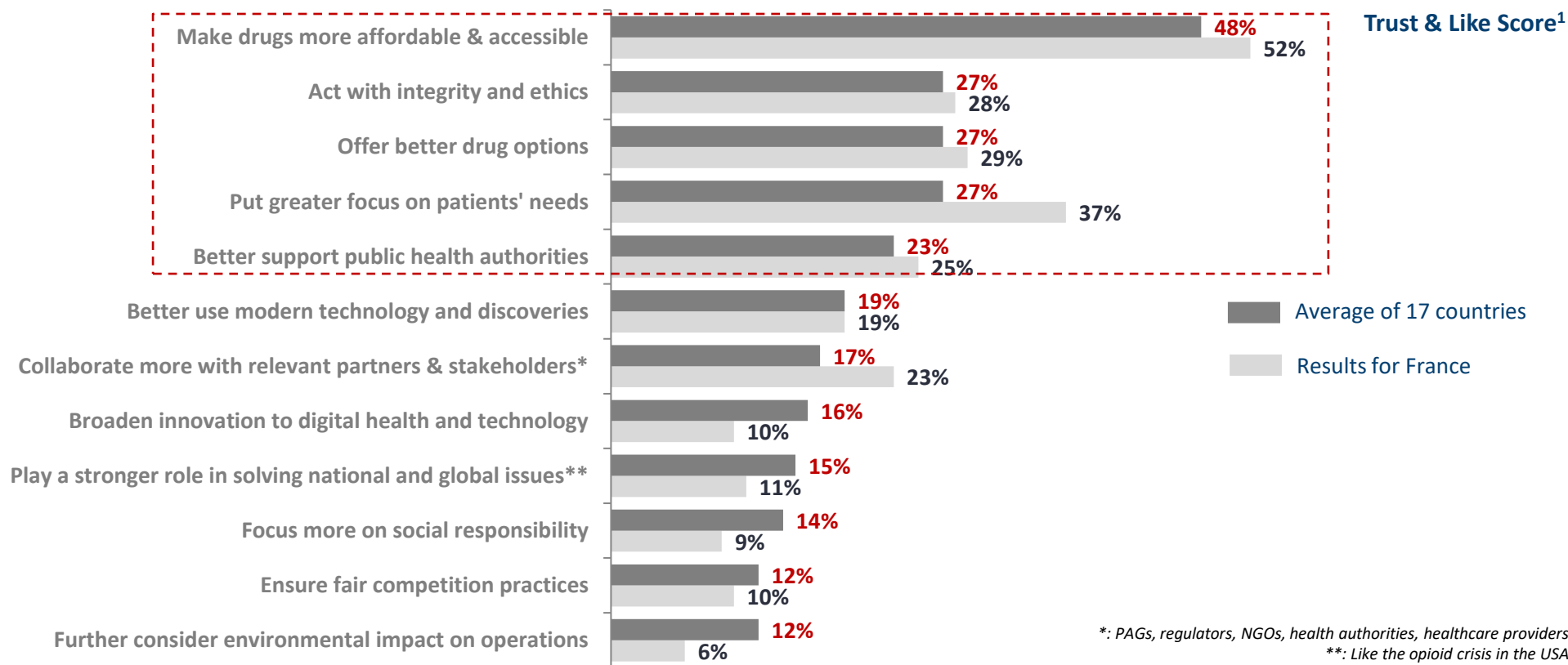
Big Pharma companies' reputation ranking by the Access to Medicine Foundation* (2021)



HCPs recommend pharma companies to revise their pricing strategy and broaden access to their innovative drugs, while better fulfilling patients' needs and supporting public health authorities

Situation analysis & Key learnings

Specific pharma companies' reputation drivers – HCPs' view (2020)



Pharma companies' reputation depends on 5 key drivers, the relative importance of which depends on individual or groups of stakeholders

Situation analysis & Key learnings

Specific pharma companies' reputation drivers – Smart Pharma Consulting's view

1. Access

- **Availability** and **affordability** of products and services...
- ... as early as possible...
- ... for **all patients** in need

2. Innovation

- Focus of R&D **investments** on diseases for which **unmet needs** are **important**; including **rare diseases**
- Development of **effective**, **well-tolerated** and **convenient drugs, services** and **therapeutic solution**, including **digital**

3. Governance

- **Compliance** with legal and ethical standards
- Implementation of a **stakeholder-driven culture**
- **Transparent** and **pro-active communication** re. business operations (e.g.; R&D, access, medico-marketing and sales)

4. Corporate Social Responsibility (CSR¹)

- Support of **good causes** (e.g.; philanthropy)
- **Positive impact** in the community
- **Respect** of the **environment**
- High standards re. **employees' management** and **satisfaction**

5. Performance

- **Achieving** or **exceeding** financial expectations
- **Growth** perspectives
- Operational **Excellence**

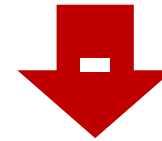
While pharma companies contribute to save and improve health of billions of people, they are regularly and heavily criticized by stakeholders for the manner they accomplish their mission

Situation analysis & Key learnings

Why is the reputation of pharma companies' damaged? (1/2)

Main criticisms from governments, HCPs, media, citizen, etc.:

- High drug costs limiting access to the wealthiest social classes and countries
- Massive profits (~32%)¹ to enrich shareholders
- Aggressive patent protection strategies, limiting access to innovative medicine
- Unethical practices to influence the prescription of HCPs
- Lack of transparency (e.g., drug pricing, clinical study results, collaborations with KOLs, etc.)



Pharma Companies' Reputation




Mission: contribution to prolong life, to improve health and wellbeing of people by developing vaccines and drugs

Pharma companies should carry out activities that are aligned with their mission, compliant with best practices and communicate properly to their stakeholders

Situation analysis & Key learnings

Why is the reputation of pharma companies' damaged? (2/2)



There is a mismatch between

 the mission and the corresponding activities



All pharma companies claim that their mission consists in improving and extending people's lives by offering products and related services

Actions enabling to accomplish their mission are not well-known, nor well-understood by stakeholders, which lead to distrust and suspicion



If stakeholders agree with pharma companies' mission...
 ... they consider that corresponding actions are not fully in line

To address their problem of reputation, pharma companies must communicate
– regularly and faithfully – about what they do and why they do it that way

Situation analysis & Key learnings

Informing and explaining to boost pharma companies' reputation

To boost REPUTATION → **Better INFORM & Better EXPLAIN**

INFORM

- Pharma companies should inform stakeholders about their strategy, performance, and key activities such as:
 - R&D
 - Manufacturing & Supply
 - Market Access
 - Medico-Marketing & Sales
- Contribution of their specific drugs to prolong life expectancy and/or quality of life should be highlighted
- Information conveyed must be fact-based, balanced and comprehensive to be trusted and to correct, possibly, misconceptions

EXPLAIN

- The most severe criticisms coming from:
 - The high price of drugs, limiting access of innovations (e.g.; vaccines against Covid-19, immunotherapies) to the least developed countries
 - The high level of profits compared to other industries
 - Certain unethical practices...
- ... thus, it is essential to give clear and defensible explanations to justify the situation
- Stakeholders should understand, for instance:
 - Why R&D costs are so high?
 - How are the prices of drugs set?
 - What is the value of marketing and sales activities?

The Pharma Reputation Booster™ is a specific multi-stakeholder approach to leverage pharma companies' corporate reputation to create a sustainable competitive advantage

Pharma Reputation Booster™

Principle

Phase 1

Situation Analysis

- Review and select **key stakeholders**
- **Profile** and **map** them
- **Measure** the **reputation** with the **Pharma Reputation Index**
- **Complete** the **Pharma Reputation Audit** highlighting company's strengths and weaknesses

Phase 2

Strategy Crafting & Tactics

- **Definite** reputation **improvement objectives**
- **Identify** and **screen** key **drivers** to strengthen corporate reputation
- Develop an **action plan**
- Select **KPIs**¹ and **KEIs**² to measure and monitor the impact of the tactics (actions)

Phase 3

Management & Leverage

- Develop an **internal communication plan** to make reputation a center piece on collaborators' agenda
- **Adjust the organization**³ to carry out the activities to strengthen the reputation
- **Design a tracking process** to correct / strengthen and leverage corporate reputation

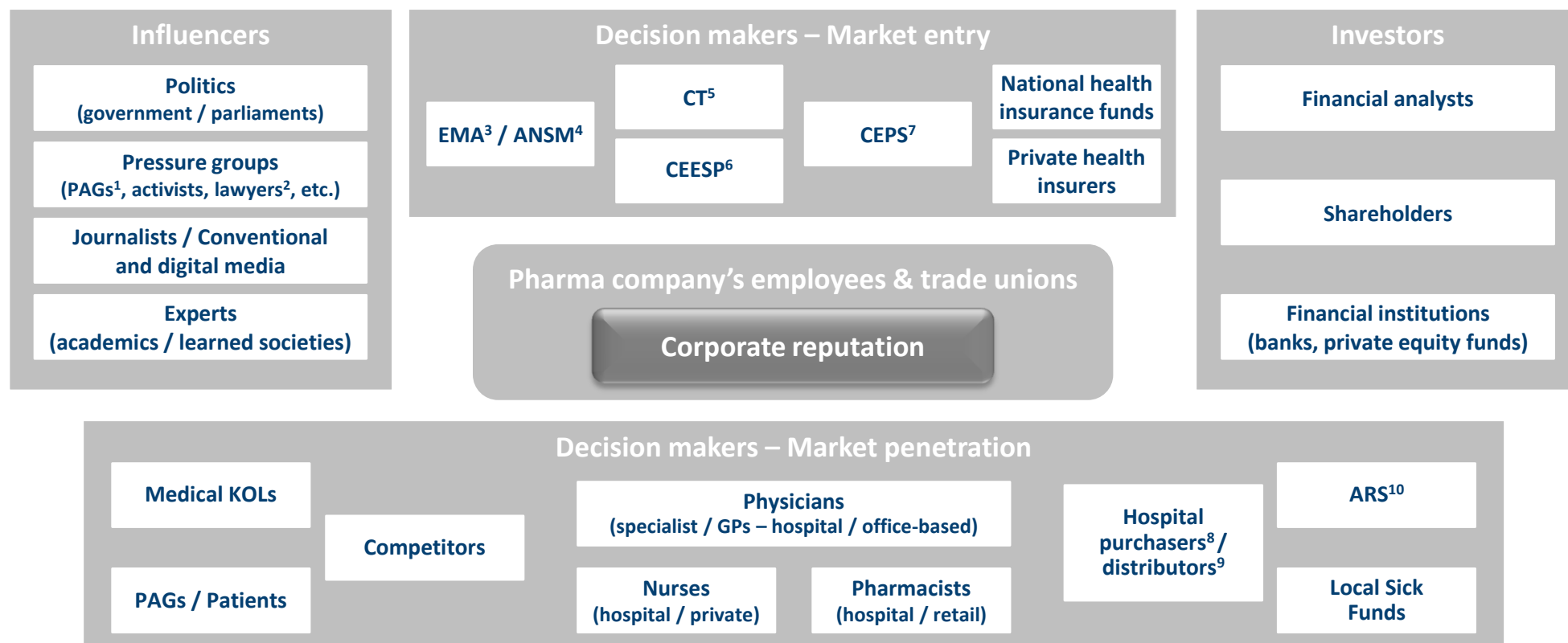
Pharma companies should review, profile and select the most influential stakeholders on their reputation, within the environment they operate

Pharma Reputation Booster™

1. Situation Analysis

Pharma stakeholders' mapping

Illustrative – France



HCPs recommend pharma

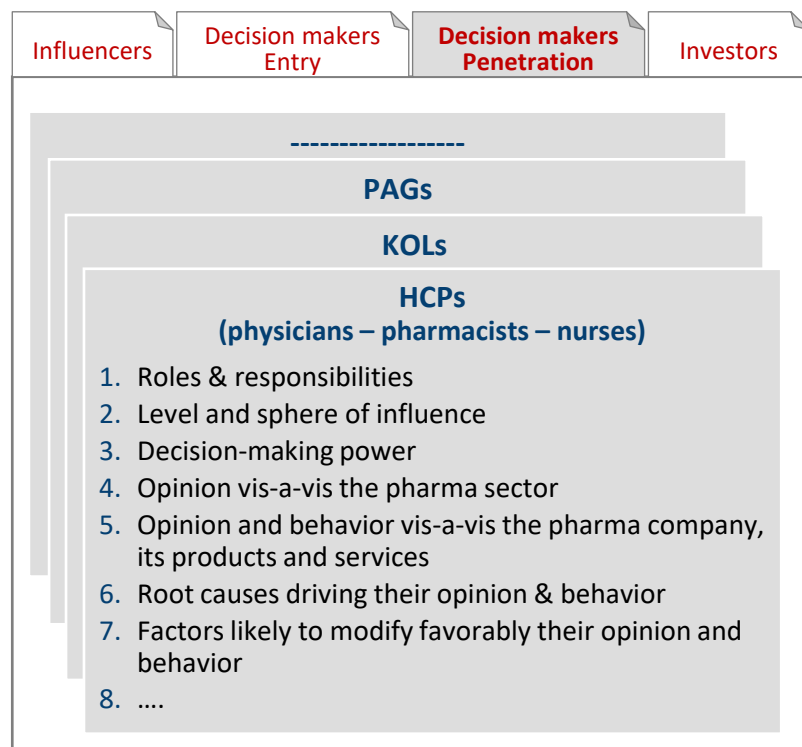
Pharma Reputation Booster™

1. Situation Analysis

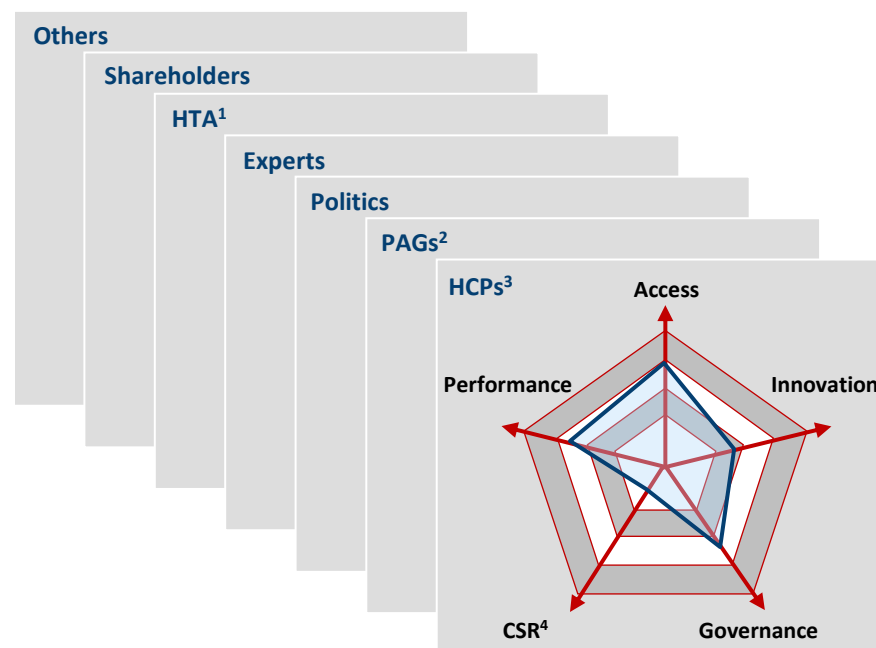
Pharma measurement of corporate reputation

Illustrative – France

Profiling of stakeholders



Performance on reputation drivers by stakeholder measure with the Pharma Reputation Index

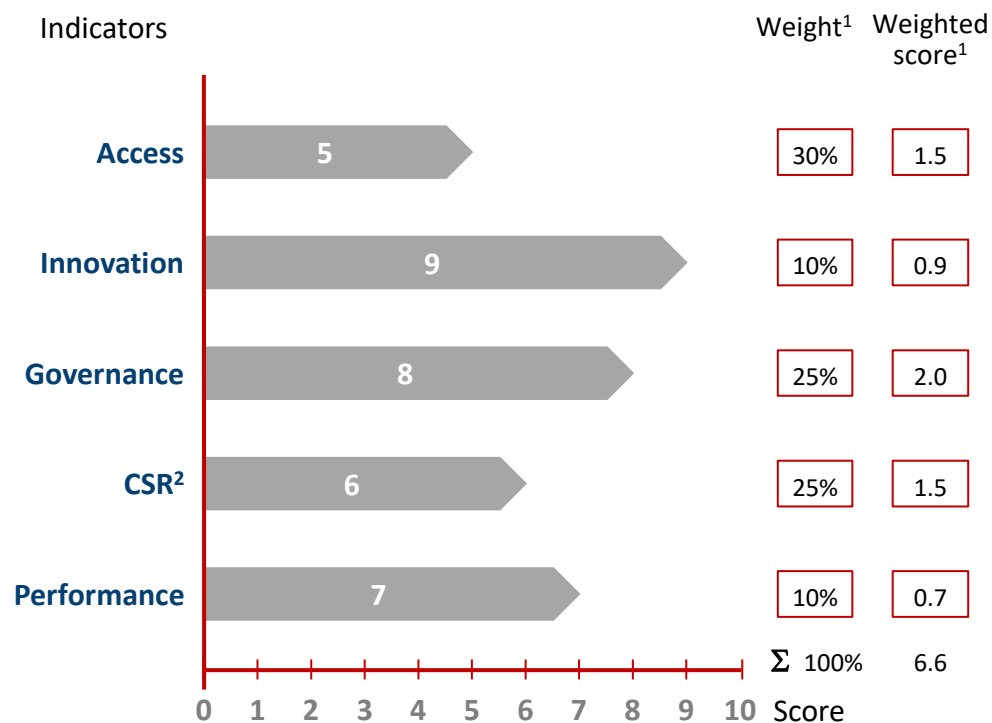


To assess the reputation of pharma companies, Smart Pharma Consulting has specifically designed the Pharma Reputation Index

Pharma Reputation Booster™

1. Situation Analysis

Pharma Reputation Index



- The Pharma Reputation Index is a tool specifically designed to assess the reputation of pharma companies and its evolution over time
- Each indicator is assessed on a 10-point scale
- The weight of each indicator will differ according to individual or groups of stakeholders (e.g.; financial performance should be more important for investors than for patients or even HCPs)
- The score obtained will reflect the extent to which the company fulfill the stakeholders' expectations
- Each evaluation should be substantiated by facts, so that to define the relevant actions to implement to improve the stakeholders' perception of the company
- The Pharma Reputation Index can be used at global and affiliate levels, directly by the pharma company or through a market study agency

The Pharma Reputation Strategy Card can be filled up for individual or groups of stakeholders, from whom an improvement in reputation is expected

Pharma Reputation Booster™

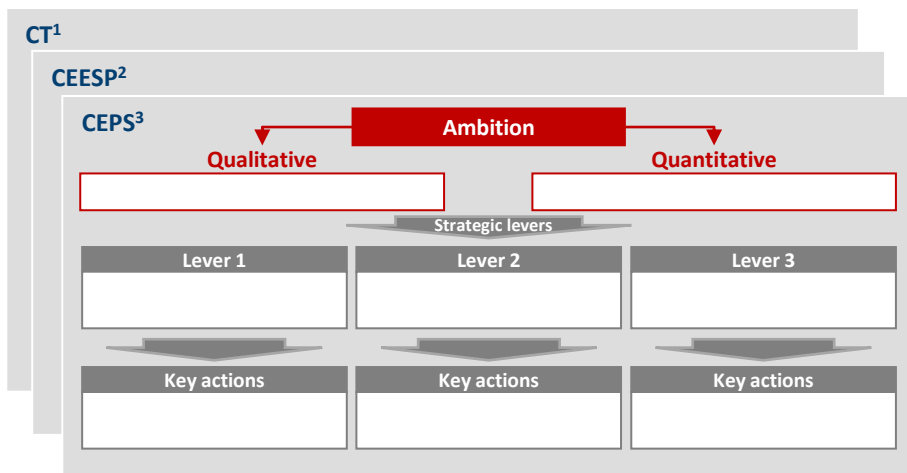
2. Strategy Crafting & Tactics

Pharma reputation strategy & tactics

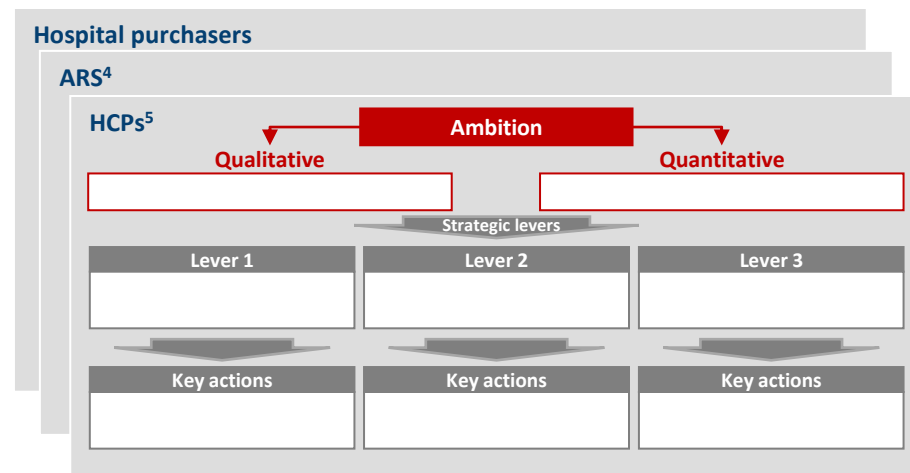
Illustrative – France

Pharma Reputation Strategy Card

Decision makers – Market entry



Decision makers – Market penetration



- Strategy and corresponding tactics aim at achieving the set ambition in terms of corporate reputation improvement
- The Pharma Reputation Strategy Card can be applied for one individual stakeholder (i.e.; the President of the CEPS, one KOL) or for one stakeholder group (i.e.; CT, CEESP, CEPS, etc.)
- Strategic levers correspond to strengths on which to capitalize or weaknesses to be corrected
- KEIs⁶ are used to evaluate the quality of implementation of tactics, while KPIs⁷ measure their impact

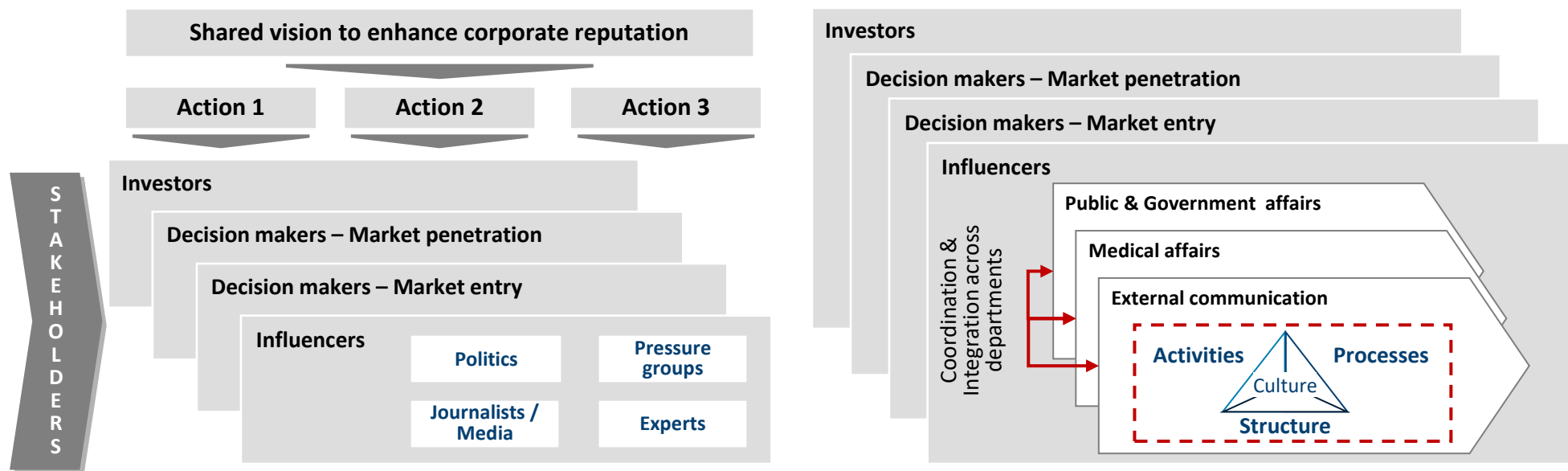
The proper management of corporate reputation is conditioned by internal mobilization of employees and by the adjustment of the company's organization to ensure operational excellence

Pharma Reputation Booster™

3. Management & Leverage

Pharma reputation management (1/2)

Illustrative – France



- A common vision, instilled by the top management and consistently communicated is a prerequisite to succeed
- Corporate vision should be translated into specific and relevant actions implemented by employees

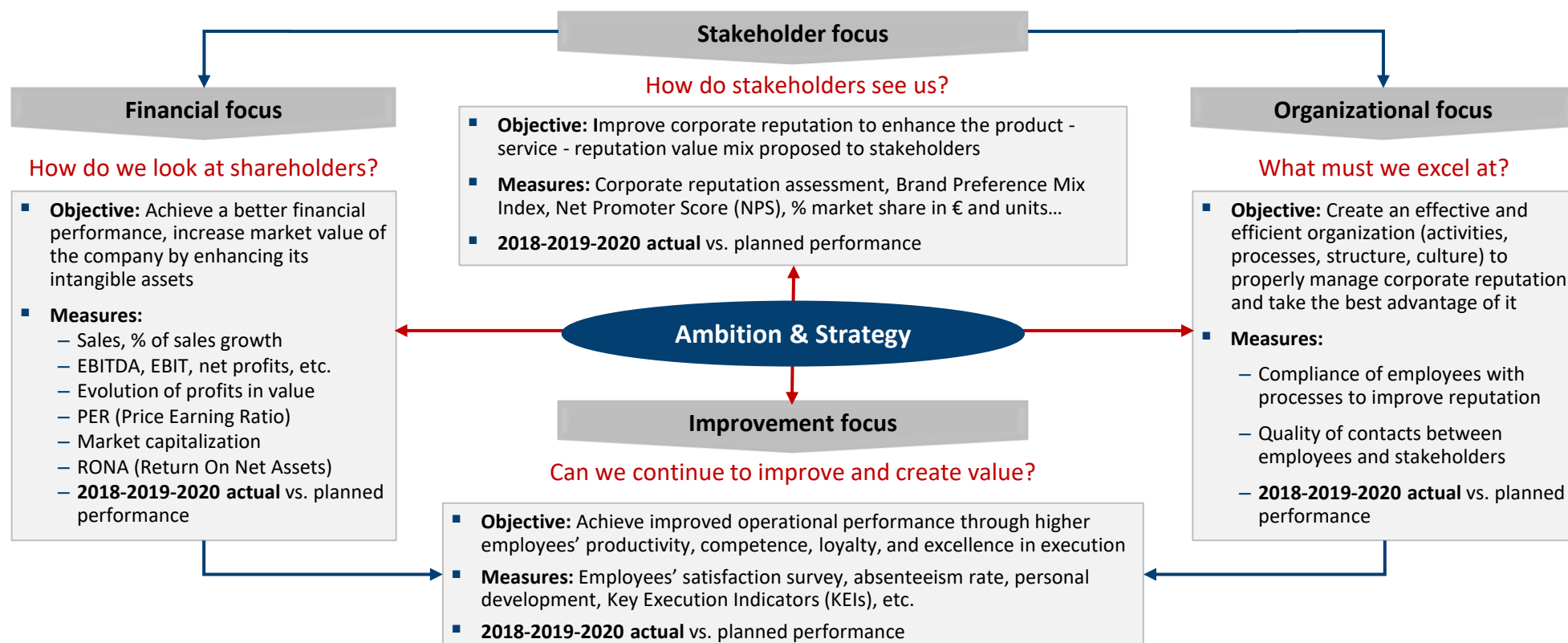
- Employees interacting with the same stakeholders should share information and coordinate their actions for a better consistency, efficiency and efficacy and thus, contribute to reinforce the corporate reputation

The corporate reputation management and its impact on the company's performance should be tracked with tools such as the following Corporate Reputation Scorecard

Recommendations

3. Management & Leverage

Pharma reputation management (2/2)



By considering what matters the most to policy makers / payers and HCPs will ease drugs market access and contribute to strengthen preference

Recommendations

Examples of initiatives to boost pharma reputation by group of stakeholders (1/2)

Illustrative

Policy makers / Payers¹

What to do?

- Develop **top-notch Corporate Social Responsibility practices** and **policies**, aligned with national mandatory schemes, and as per ISO 26000 guidance
- Build **outstanding value** dossiers from the **viewpoint** of Health Technology Assessment (HTA) **reviewers**
- Adopt a **pricing strategy** supported by **well-founded arguments** likely to be understood by payers
- **Invest** in **national economy**, but with caution³

How to do it?

- Carry out **environmental initiatives** (e.g.; electric cars), support **philanthropic projects**, give **wide access** to drugs and vaccines in **lower income countries**
- Pay a great attention to the **robustness** of the value dossier **content** and to the **quality** of the **page layout**
- **Be transparent** on R&D costs and develop **defendable arguments** to support the requested drug price
- **Productive** and **R&D** investments are the **best valued**

Health Care professionals²

- Provide HCPs with **objective** and **transparent information** re. company's **pipeline**, **promoted brands** and **diseases** they address
- Propose **meaningful services** for:
 - HCPs, themselves
 - Their patients or...
 - ... the institution for which they work

- **Strictly comply** with local **regulations** and business **ethics** in terms of **communication** to HCPs and **services** provided
- Carefully **pre-assess** the usefulness, interest, convenience and likely quality of execution of a **service** before proposing it to HCPs
- **Inform** other stakeholders **about the benefits** of **services delivered**, through testimonies, etc.

Employees are the primary source of reputation for most of external stakeholders, along with the quality of products and services offered by the pharma companies

Recommendations

Examples of initiatives to boost pharma reputation by group of stakeholders (2/2)

Illustrative

Patients / Patient Advocacy Groups¹

What to do?

- Beyond offering drugs, **develop** – whenever relevant – **Patient Support Programs (PSP)** to get **better medical outcomes** and improve **quality of life**
- Propose **services** at the **awareness, diagnosis, prescription** and/or **monitoring steps** of the patient journey to address / prevent potential dysfunctions
- Give **access** to **information** and to **personalized tools** on **Internet** for **patients** and **PAGs**

How to do it?

- **PSP** should be **co-developed** in partnership **with PAGs, HCPs** and other stakeholders involved in the management of the pathology
- **Programs** should be **easy to implement**, the quality of **execution** should **excellent**; and the **results** be **significant, measurable** and widely **communicated**
- **Develop** or **co-develop** community **websites** for patients, **give access** to an **e-library**, to **specific Apps**, etc.)

Employees

- **Demonstrate** a **sense of purpose** across environment, social, and governance (**ESG**) topics, including Diversity & Inclusion (**D&I**) management, to **attract candidates, retain employees** and **convert them into** companies' **ambassadors** to external stakeholders
- Instill a **culture of excellence** to deliver **superior services** and thus superior **experience** to external stakeholders when compared to competitors

- Maintain a **good working atmosphere** based on trust, respect, positiveness, cross-functional collaborations and personal development
- **Engage employees** in **CSR initiatives** that will **make them proud** to work for the company
- **Create the conditions to stimulate** the **passion** of employees **for their job** to prompt them to give their best (e.g.; flexible work arrangements, recognition, rewards, autonomy)²

Pharma companies should adjust their communication in terms of content and channels to the expectations of their stakeholders, with a priority given to their own employees

Recommendations

Five communication rules to strengthen pharma companies' reputation

Rule #1

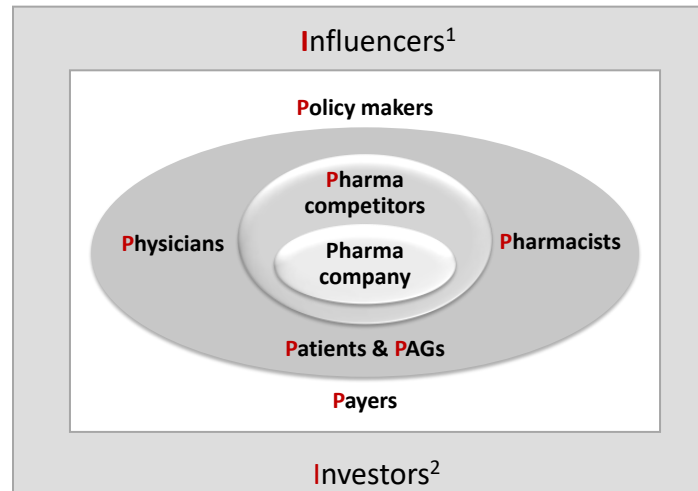
Focus on your **company's reputation** and not on the pharma sector's reputation on which you cannot do much

Rule #5

The **most important stakeholders** you must engage are **your employees** who directly participate to your reputation

Rule #2

Inform and explain your employees and your external stakeholders **about** your **strategic priorities** and the **implementation** of the corresponding **tactics** (activities)



Rule #3

Adjust the **content** of your **communication**, knowing that different stakeholders are sensitive to different drivers

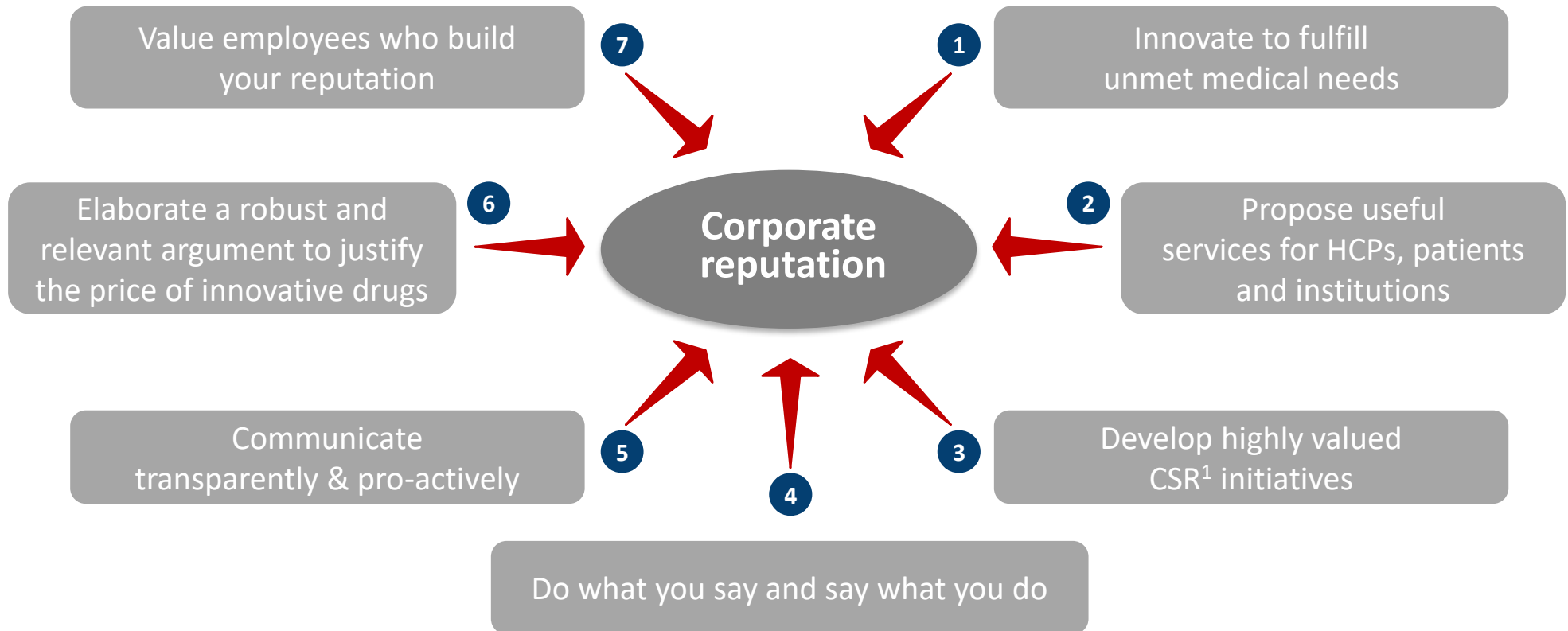
Rule #4

Adapt the communication **channels** to the **information** you want to convey and to the targeted **stakeholders**

Pharma companies must put their stakeholders in the center of their strategy, “walk the talk”, and be as transparent as possible to get trusted, esteemed and preferred

Recommendations

7 imperatives to improve the reputation of pharma companies

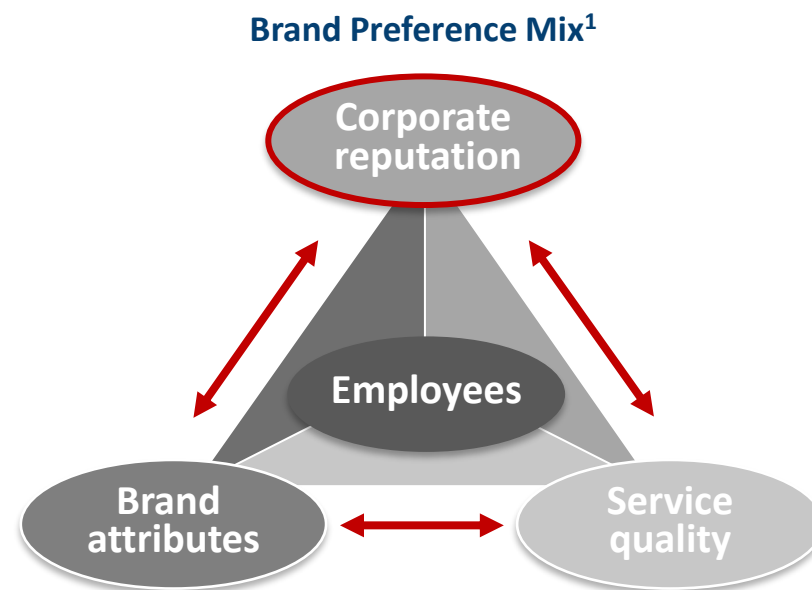


With dwindling drug differentiation, pharma corporate reputation contributes to strengthen the preference of stakeholders (e.g.; authorities, payers, HCPs, patients, investors)

Recommendations

Why superior pharma reputation creates competitive advantage?

- Correlation between financial performance and corporate reputation has been clearly evidenced over the past 20 years
- Higher corporate reputation, than competitors' one:
 - Leads to a more favorable position to negotiate with health authorities and payers, resulting in earlier market entries and better prices
 - Strengthens brand preference by KOLs, HCPs, PAGs, patients, etc., resulting in market share optimization
- Pharma companies' experience / expertise in specific therapeutic areas must be communicated with robust scientific evidence to enhance the perception of brands value by decision makers at market entry and penetration levels
- Strong positive reputation is built on credibility, reliability, responsibility, trust and transparency



The Brand Preference Mix is an easy and effective approach to strengthen the preference of stakeholders for marketed brands

“Boosting corporate reputation contributes to reinforce stakeholders’ preference and companies’ performance”

If you have ticked one “No box” or more, it means that there is a room to enhance your corporate reputation

Recommendations

Pharma corporate reputation self-assessment in 10 questions

Most of stakeholders (influencers – decision makers – Investors) are aware and esteem¹ ...

	YES	NO
1 ... Your high level of R&D investment and your effort to fulfill medical unmet needs, including in rare diseases	<input type="checkbox"/>	<input type="checkbox"/>
2 ... The quality of your product pipeline and of your marketed brands	<input type="checkbox"/>	<input type="checkbox"/>
3 ... The quality of services you propose to HCPs and/or to the organizations in which they practice	<input type="checkbox"/>	<input type="checkbox"/>
4 ... The quality of services you propose to patients / PAGs for better medical outcomes and improved quality of life	<input type="checkbox"/>	<input type="checkbox"/>
5 ... Your involvement in “Corporate Social Responsibility” initiatives	<input type="checkbox"/>	<input type="checkbox"/>
6 ... Your philanthropic initiatives	<input type="checkbox"/>	<input type="checkbox"/>
7 ... Your pro-active and transparent corporate communication	<input type="checkbox"/>	<input type="checkbox"/>
8 ... The professionalism and the ethical behavior of your employees	<input type="checkbox"/>	<input type="checkbox"/>
9 ... The working atmosphere of your company, as testified by your employees	<input type="checkbox"/>	<input type="checkbox"/>
10 ... The good and sustainable financial performance of your company	<input type="checkbox"/>	<input type="checkbox"/>

Smart Pharma Consulting experience and methodology can help pharma companies boost their corporate reputation to strengthen their competitive position and their performance

Recommendations

How can Smart Pharma Consulting help you boost your corporate reputation?

Smart Pharma Consulting can **support** pharma companies and their affiliates **throughout** all the phases that participate to **build a strong corporate reputation** and **transform it** into a **sustainable competitive advantage**:

- Research and **assessment** of your **current** corporate **reputation** among individual or groups of stakeholders
- **Definition** of a realistic corporate reputation **enhancement objective** by individual or group of stakeholders
- Development of an **appropriate strategy** and selection of the corresponding **tactics (actions)** to achieve your reputation enhancement objective
- Selection of the **KEIs**¹ and the **KPIs**² to **measure the gap** between the current and the improvement objective
- Development of a **communication plan (internal and external)** and of a **management program** to create a stakeholder-focused company
- **Adjustment** of the company's **organization** (activities, processes, structure, culture) to efficiently **implement** the **strategy** and the corresponding **tactics (actions)**, and to **leverage** the **benefits** of an enhanced corporate reputation
- **Design** of a **tracking process** to improve and leverage corporate reputation

“Select two or three dimensions and strive to be recognized as a role model by stakeholders to differentiate your company from other pharma companies”

Best-in-class **Pharma BD&L**

BEST-IN-CLASS SERIES

From theory to practice

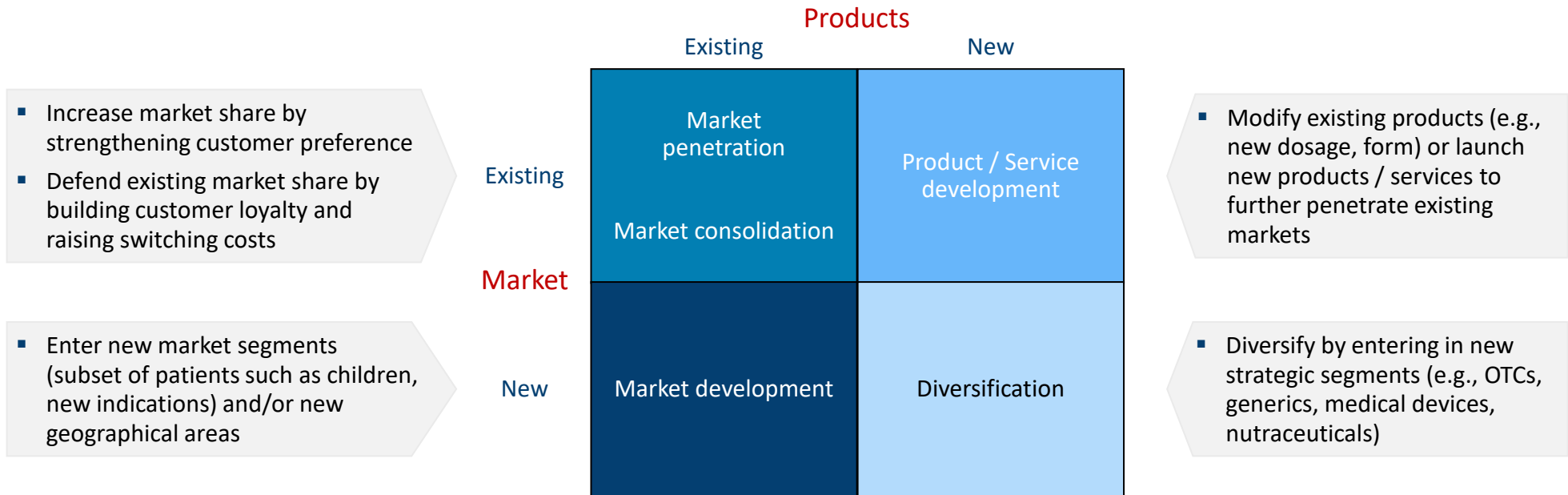
BD&L opportunities being rare and complex, Pharma BD&L managers would be well-advised to adopt a systematic, rigorous and perfectly planned approach

Key points addressed

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

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

Alternative directions to ensure strategic development

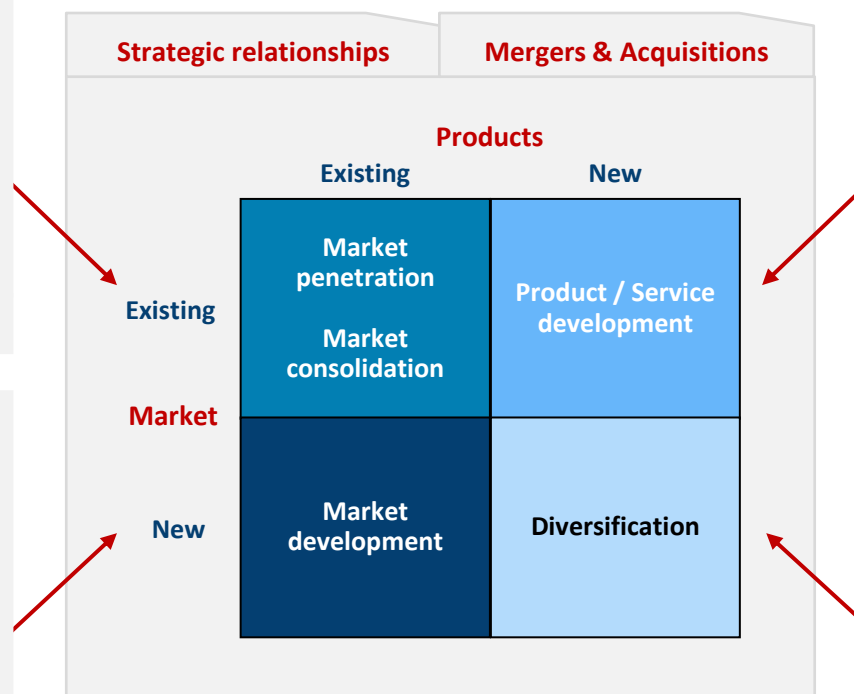


BD&L refers to strategic relationships or Merger & Acquisition deals which enable affiliates to grow and strengthen their competitive position

Definition of BD&L

- Collaboration with a third party (e.g., pharma company, CSO¹) to increase share of contacts and/or share of voice
- Co-marketing or co-promotion agreements to increase resources behind one molecule
- Acquisition of competitors to reduce or better manage competitive intensity

- Collaboration with a CRO² to develop new indications
- Co-promotion with a partner to promote to a group of new clients (e.g., pediatricians, neurologists)
- Licensing-out to a third party to:
 - Market in new countries (e.g., biotech products in Africa)
 - Expand presence in second priority territories (e.g., in Mexico, South Africa, India)
 - Etc.

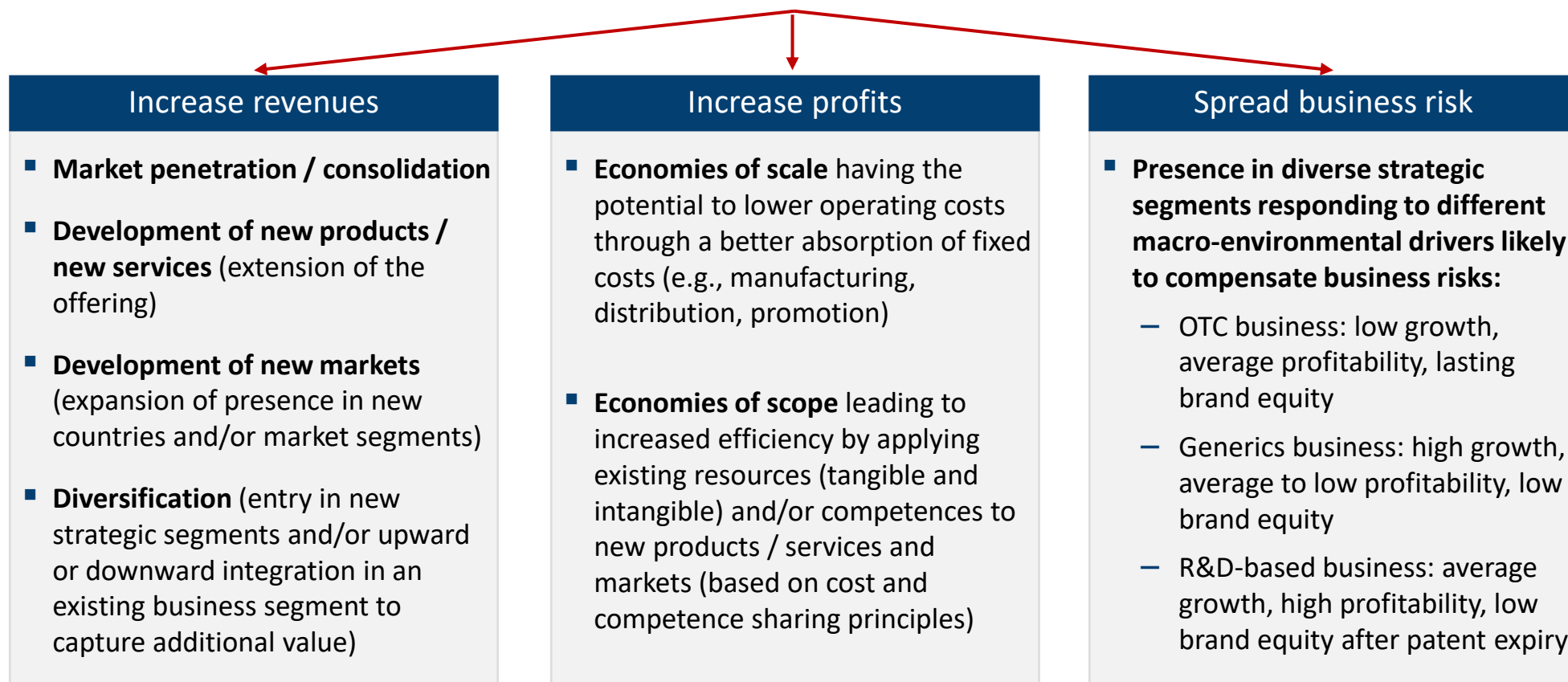


- Outsourcing development of a new combined formulation
- Co-branding of a diagnostic tool and of a drug for a given pathology (e.g., diabetes, hypertension, oncology, etc.)
- Co-development of back-up brands (i.e., isomers, active metabolites, esters, salts of existing molecules)
- Acquisition or in-licensing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

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

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

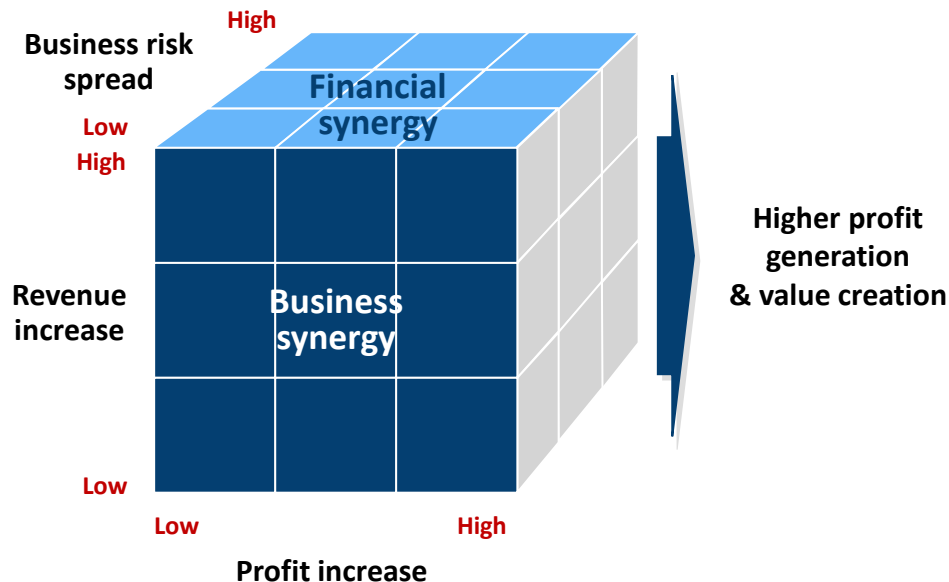
Expected benefits from BD&L initiatives



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

Synergy applied to business development

Types of synergies in the context of BD&L



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

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

Capability building through business development

Strategic relationships

- Strategic alliances involve the sharing of capabilities (resources + competences) in pursuit of common goals
- Outsourcing, which is a form of subcontracting, enables affiliates to access capabilities by borrowing them from other companies (e.g., deals with a CSO¹ or another pharma company)
- Accessing capabilities through alliances offers more targeted and cost-effective means than acquisition
- Where both partners are trying to acquire one another's capabilities, results may be a "competition for competence" that ultimately destabilizes the relationship

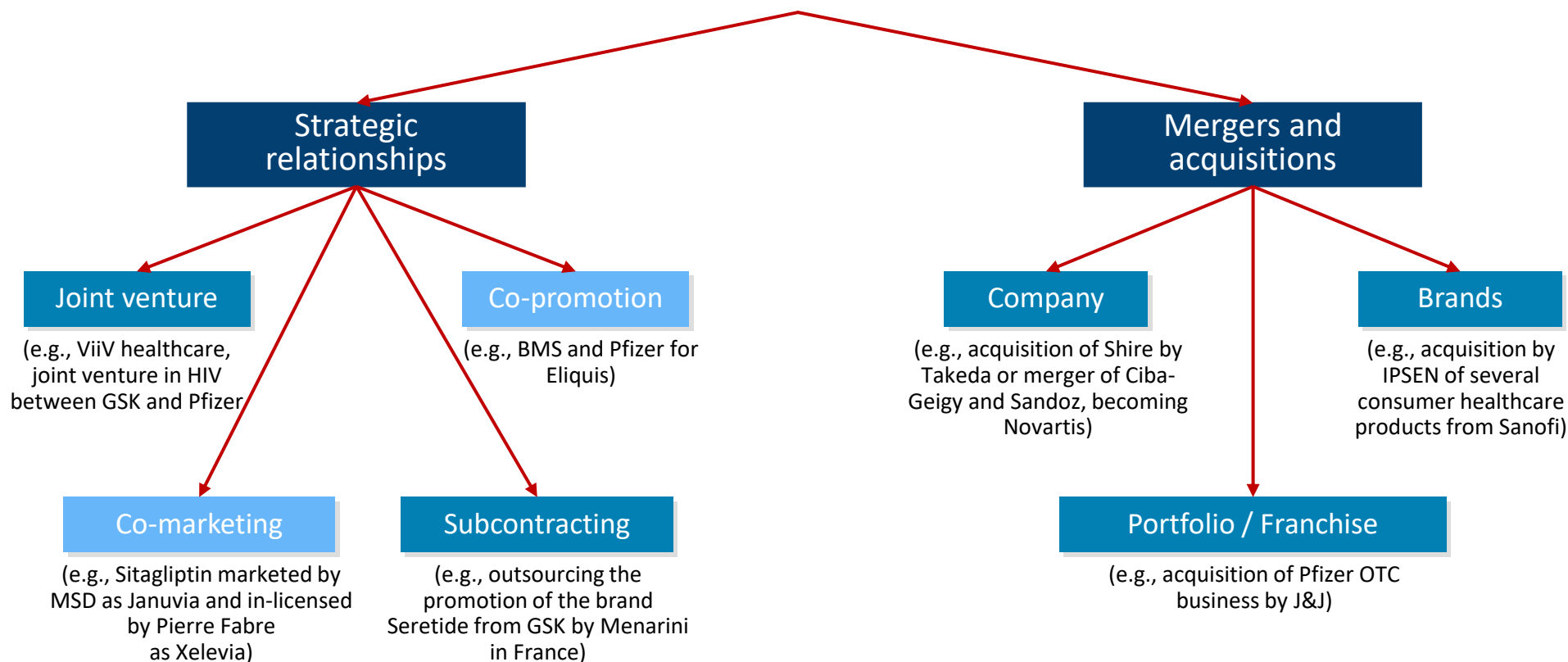
Mergers & Acquisitions

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

Note: Capabilities can grow internally by systematizing their replication through the formulation and the implementation of SOPs²

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

Typology of BD&L deals



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

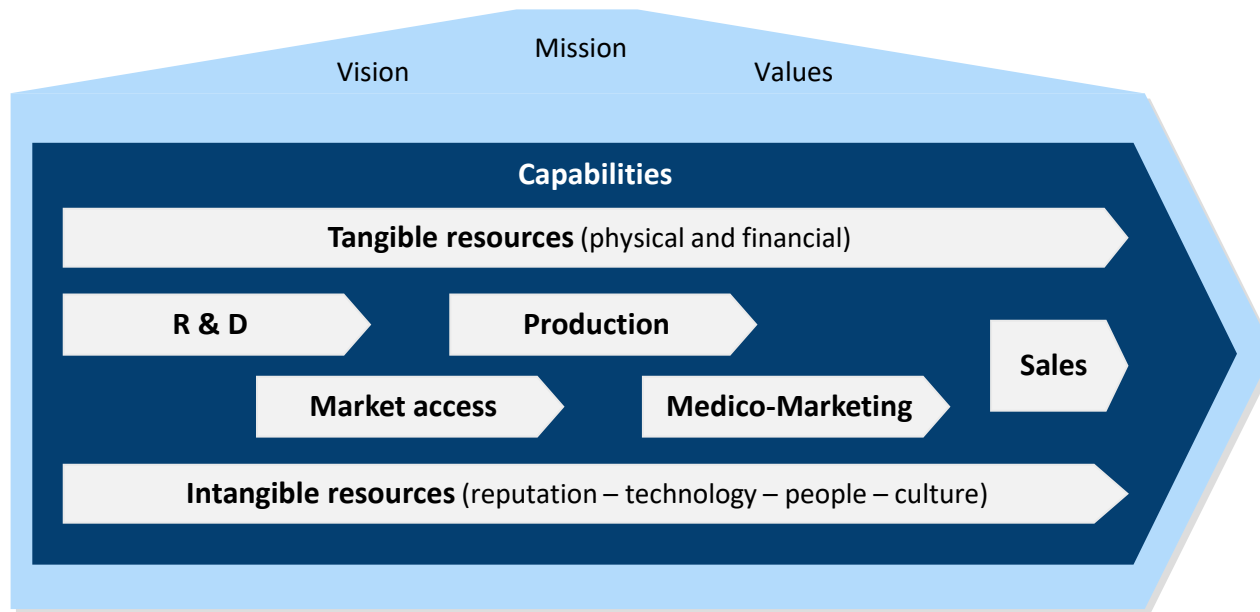
Pros and Cons of co-marketing and co-promotion agreements

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

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

Methodology to assess business opportunities

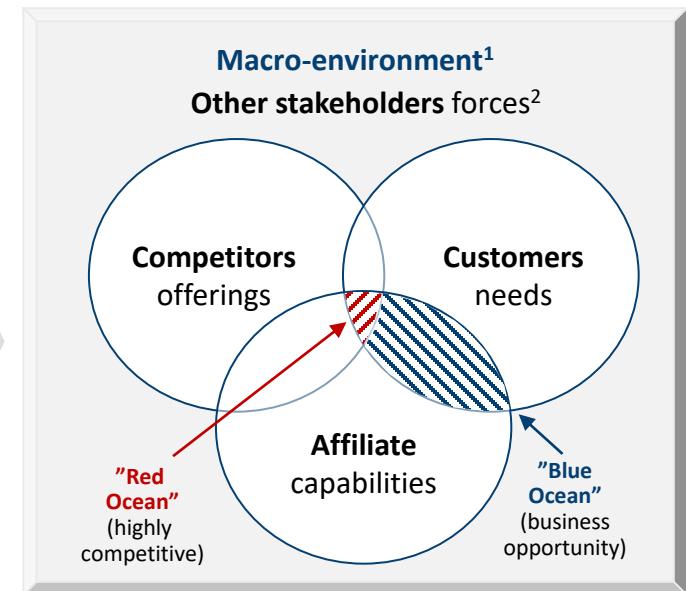
Business model



Strengths & Weaknesses
(Competitive advantage)

Strategic segments

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

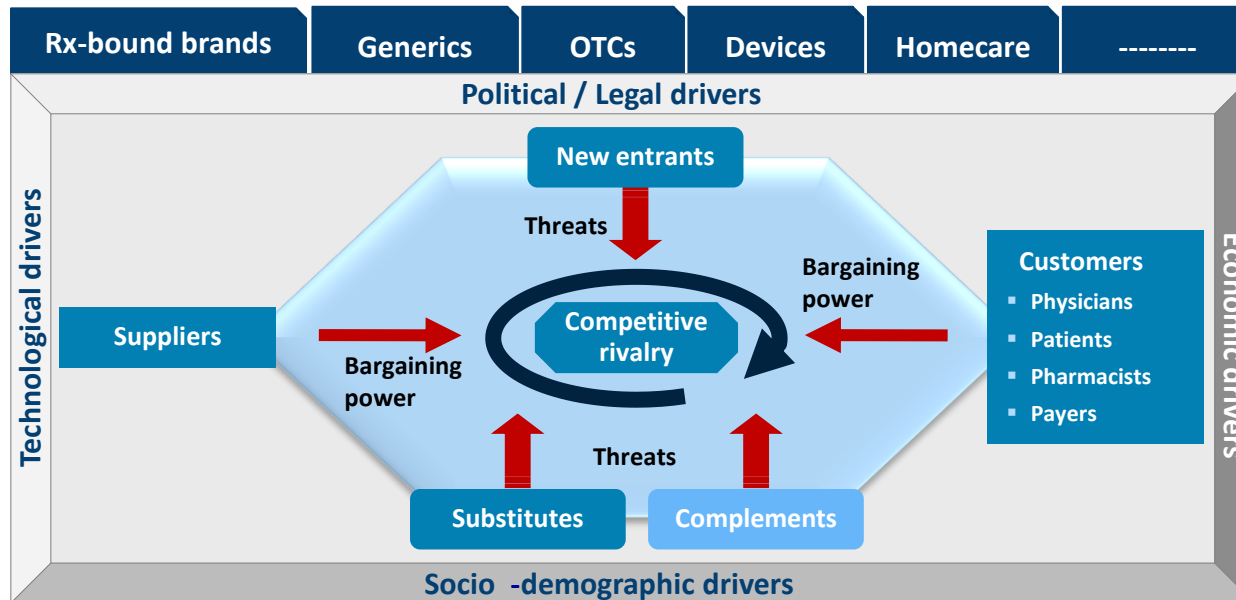


Opportunities & Threats
(Attractiveness & Key success factors)

Ambition & Strategic priorities

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

Attractiveness of strategic segments (1/3)



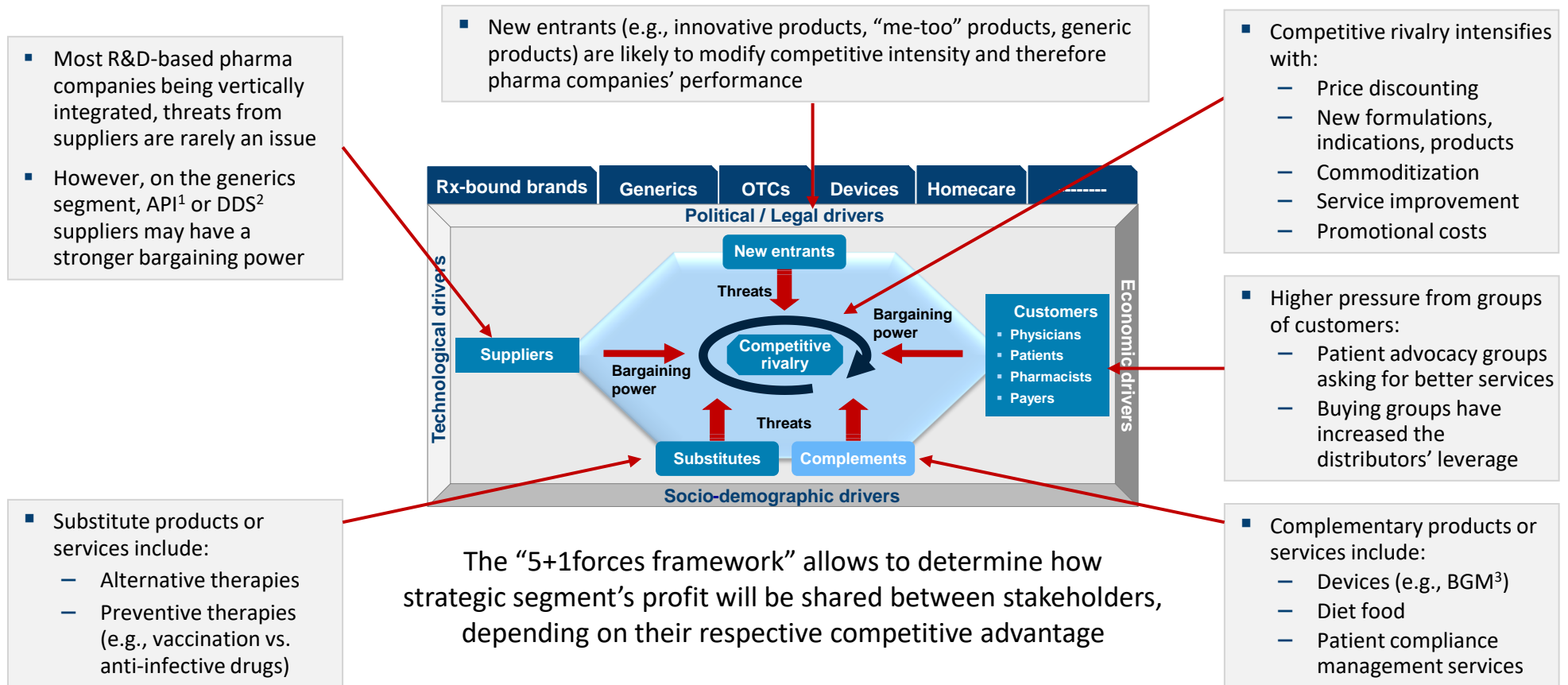
- The four key macro-environmental drivers:
 - Political / Legal
 - Economy
 - Socio-demography
 - Technology
- The five key micro-environment drivers:
 - Suppliers
 - Customers
 - New entrants
 - Substitutes
 - Competitive rivalry
- ... plus, the “Complements” influence the attractiveness of each strategic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

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

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

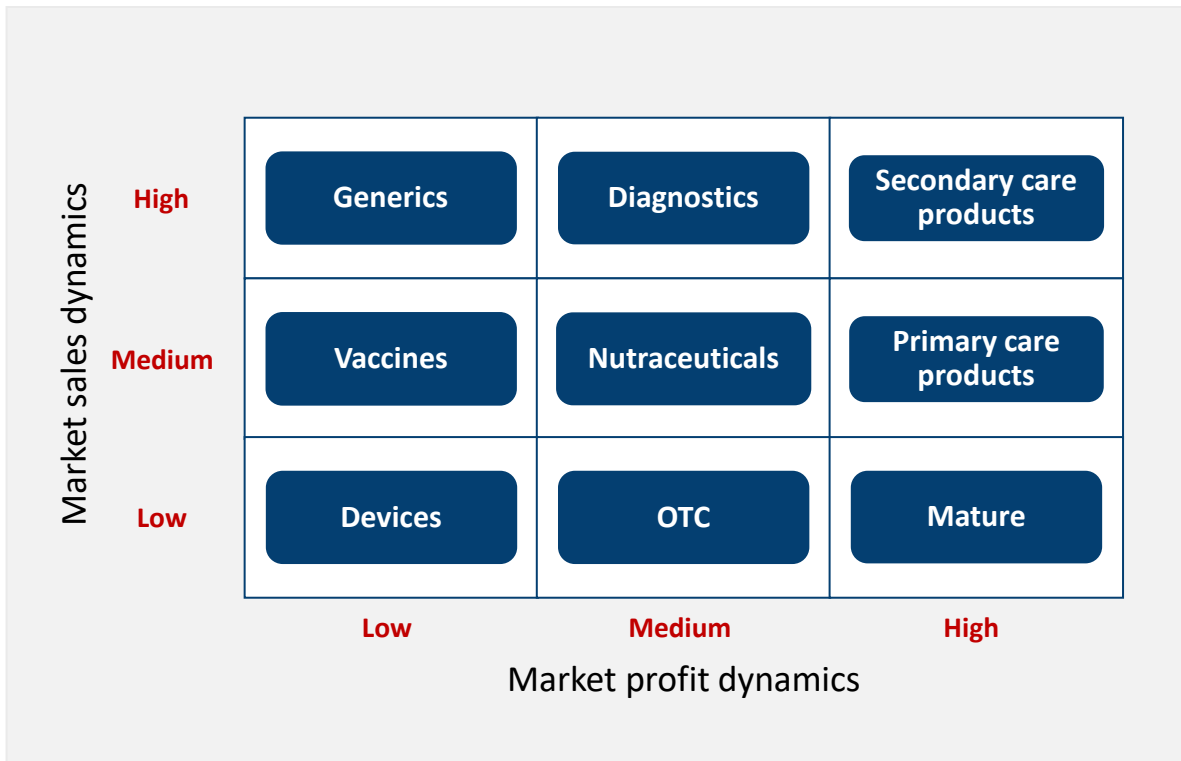
The “5+1 forces framework” is particularly helpful to identify the key stakeholders that will influence the long-term structure and profitability of strategic segments

Attractiveness of strategic segments (2/3)



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

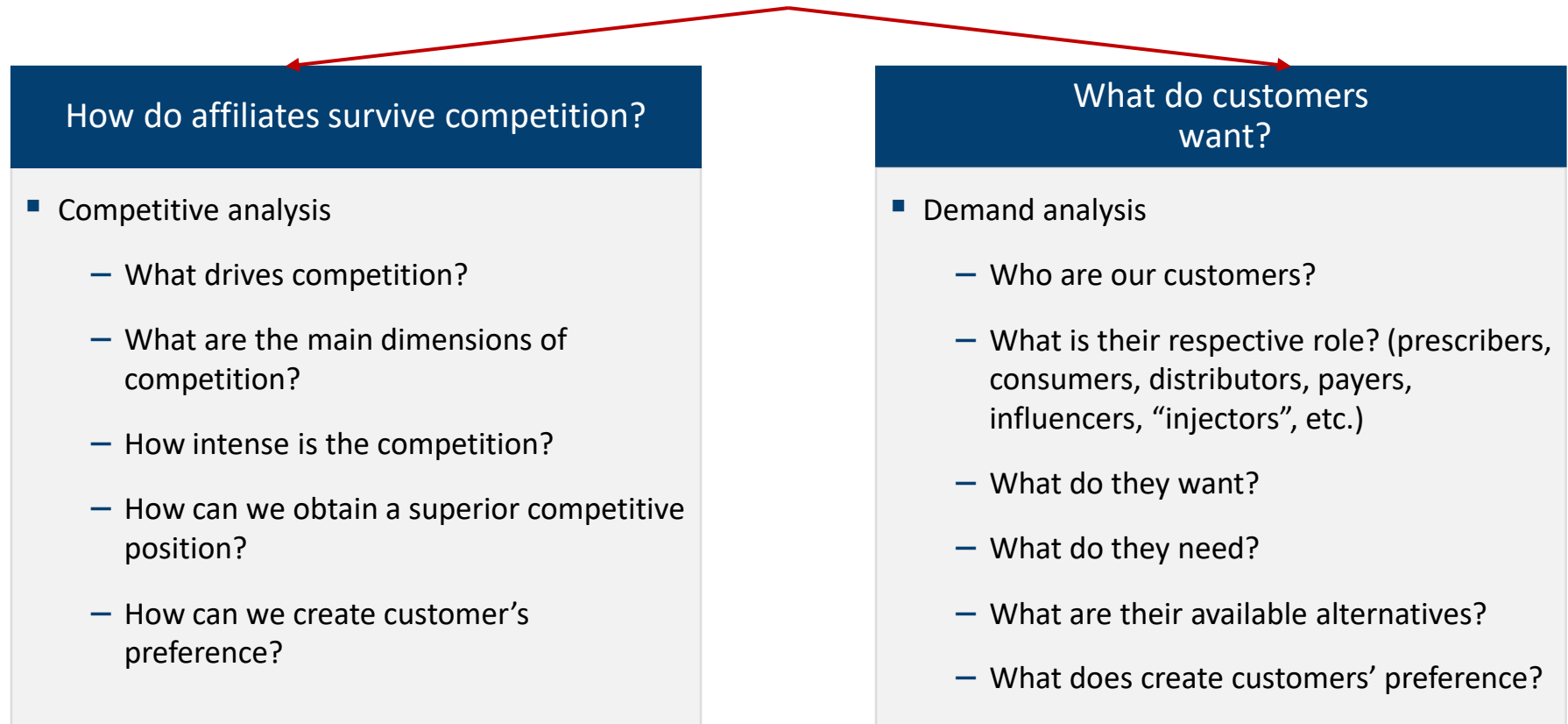
Attractiveness of strategic segments (3/3)



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

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

Key success factors by strategic segment



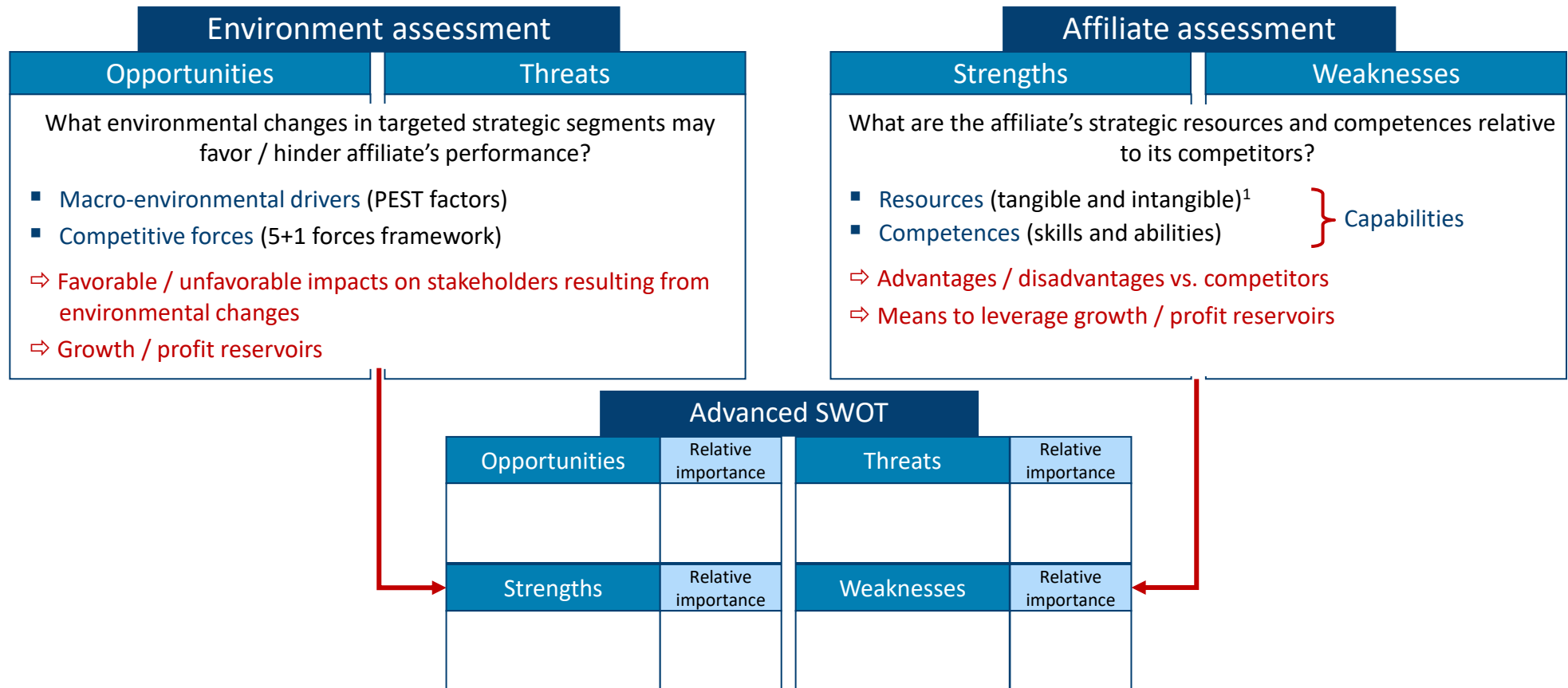
Strategic priorities should be set after capabilities assessment to outperform competitors on key success factors inherent to each targeted strategic segment

Affiliate's competitive advantage and strategic priorities



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







Advanced SWOT analysis



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

Strategic options and strategic segment card

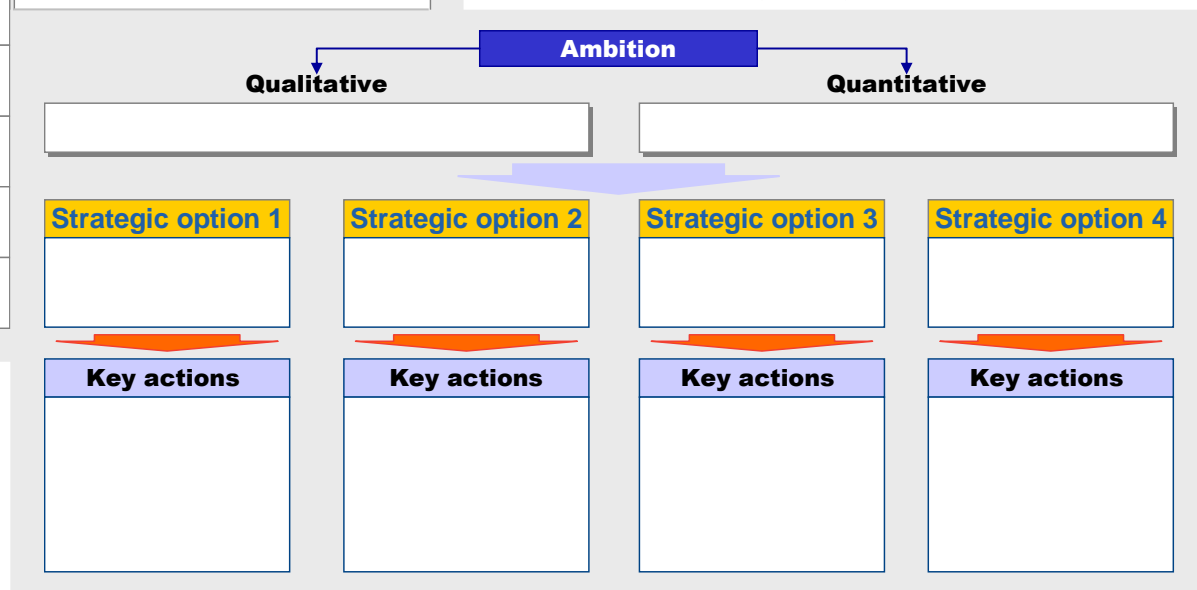
Strategic options

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



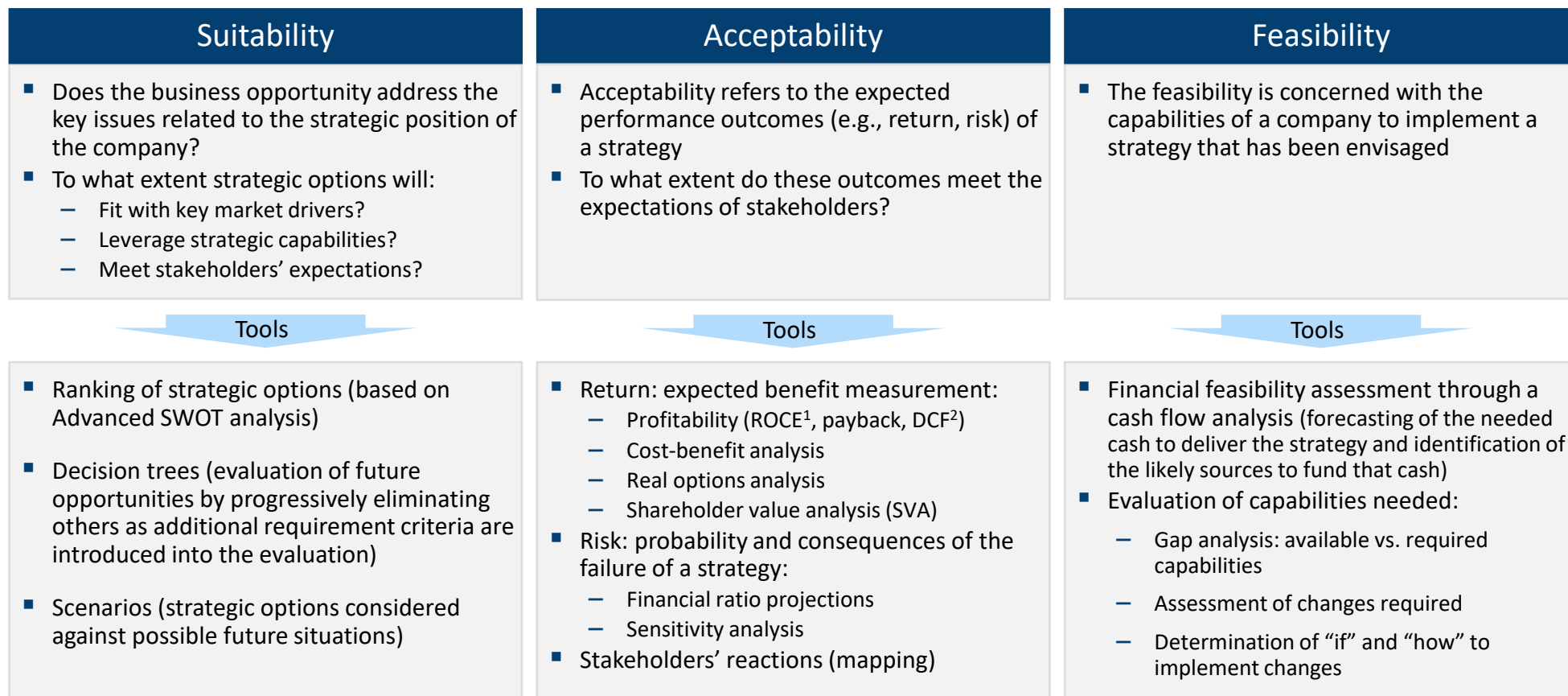
++ Major strength + Minor strength = Neutral
 - Minor weakness -- Major weakness

Strategic segment card



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

Evaluation of business development opportunities (1/2)



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

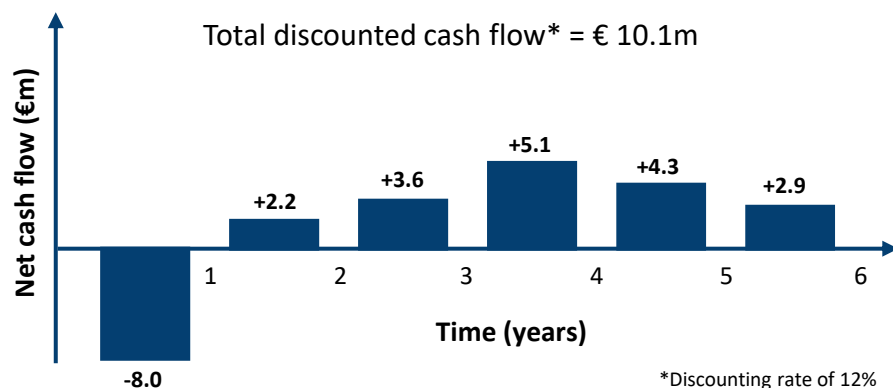
Evaluation of business development opportunities (2/2)

Examples of acceptability criteria

Illustrative

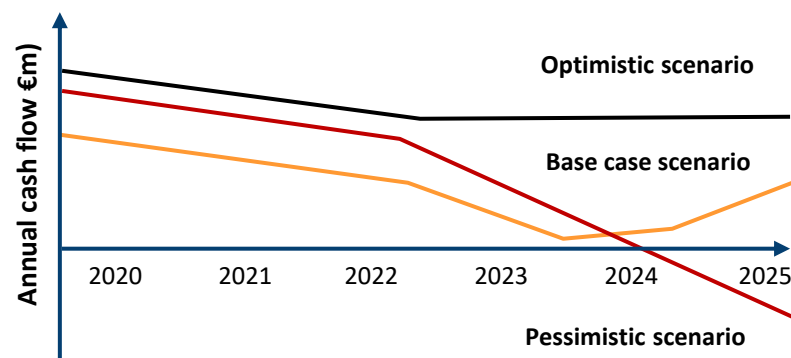
Return: Discounted cash flows (DCF)

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



Risk: Sensitivity analysis

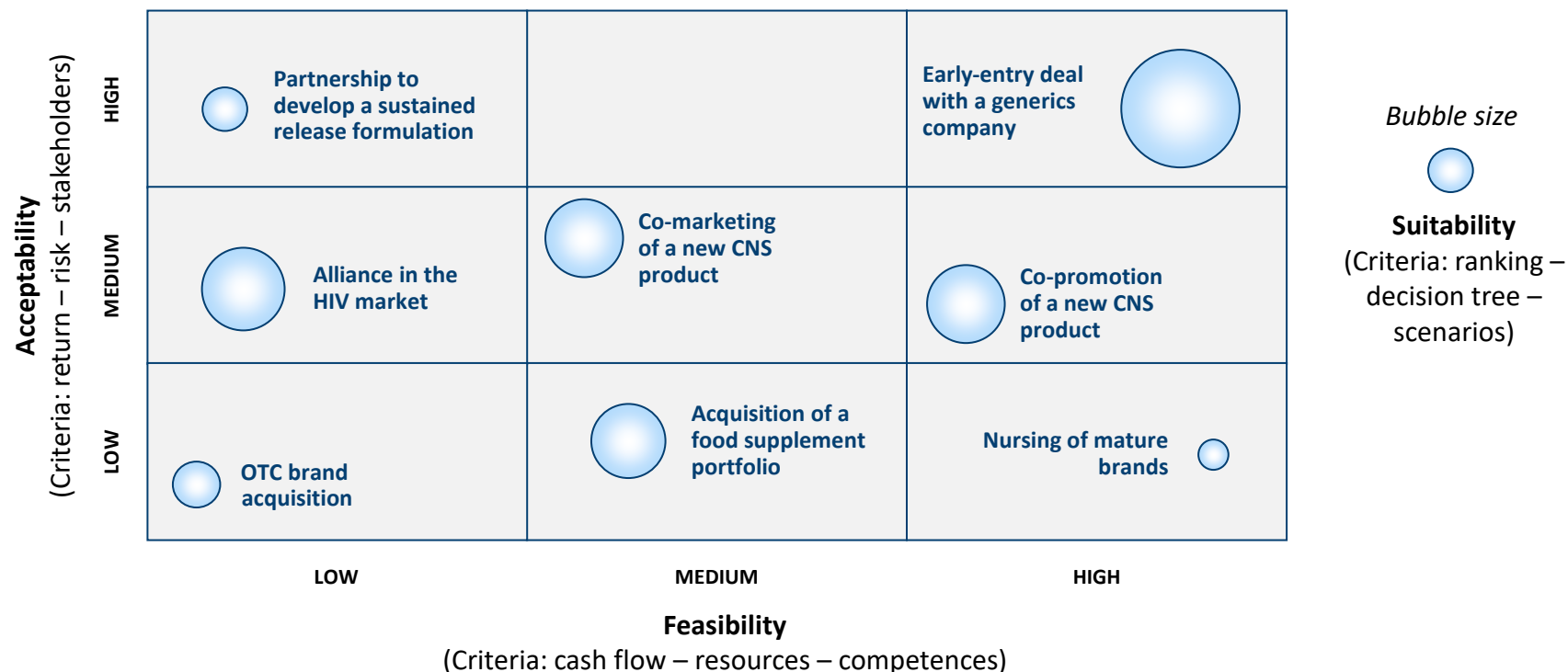
- Sensitivity or “what if” analysis is a useful technique for assessing the extent to which the success of a preferred business development opportunity is dependent on the key underlying assumptions, such as sales forecasts, price changes, investment requirements, new entrants, etc.
- This analysis helps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



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

Business development evaluation matrix

Illustrative

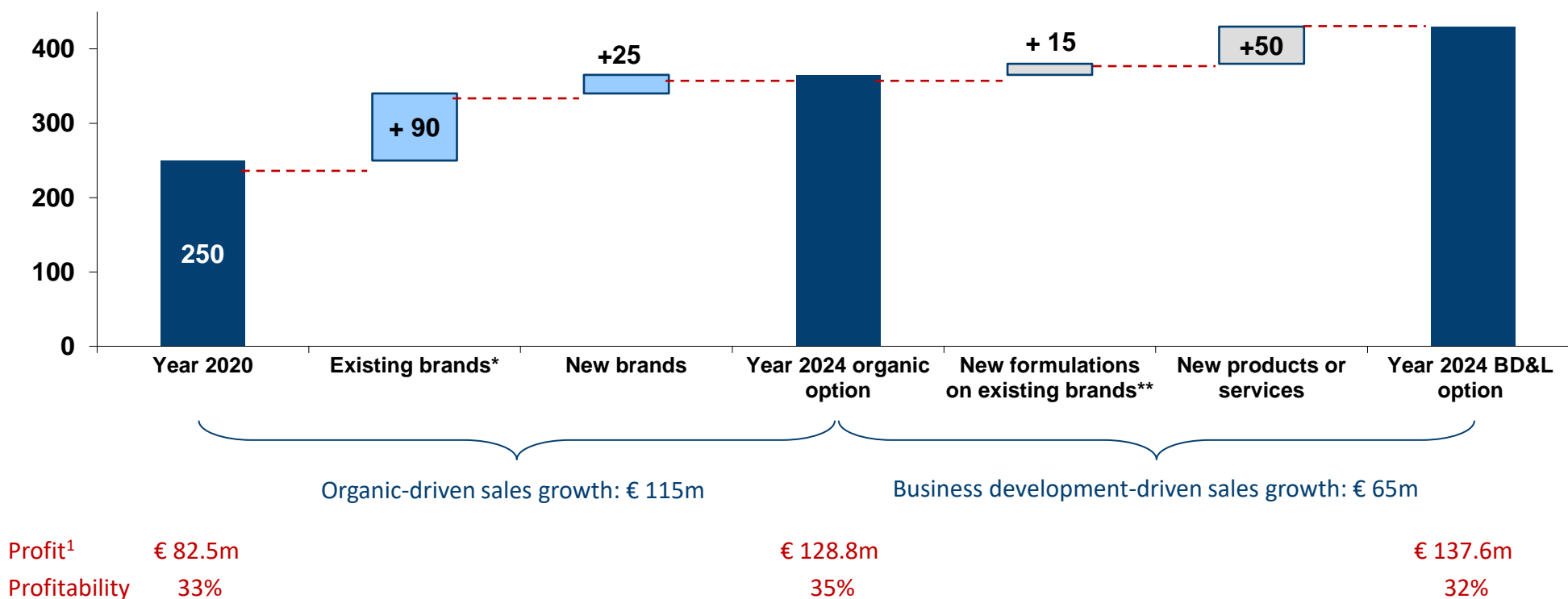


In general, business development deals boost sales and profit growth, while altering profitability, due to profit sharing agreement and resulting organizational dysfunction

Impact of business development initiatives

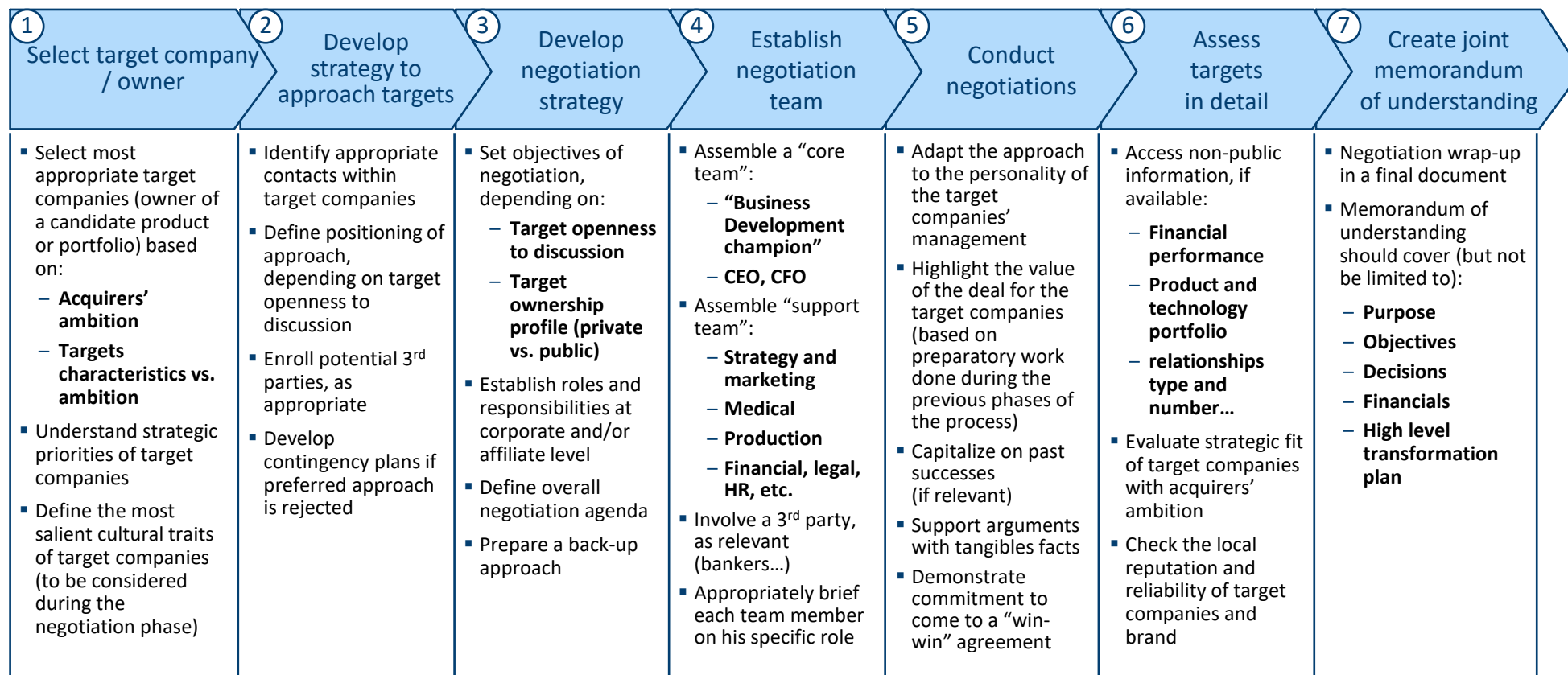
Illustrative

Sales in €m



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

Process to approach target companies

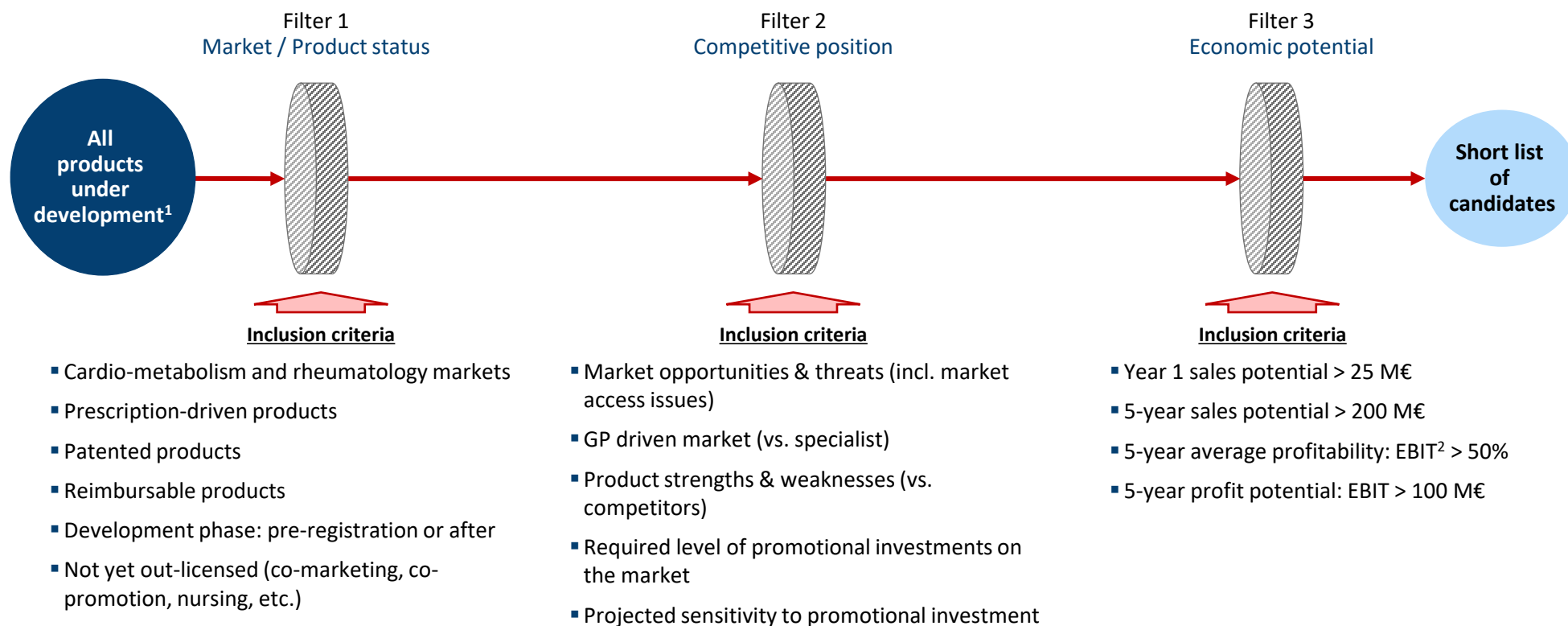


The selection of most attractive candidate products under development, within a defined strategic segment, can be established through the following methodology

Under-development product screening

Rx-bound products in France

Illustrative

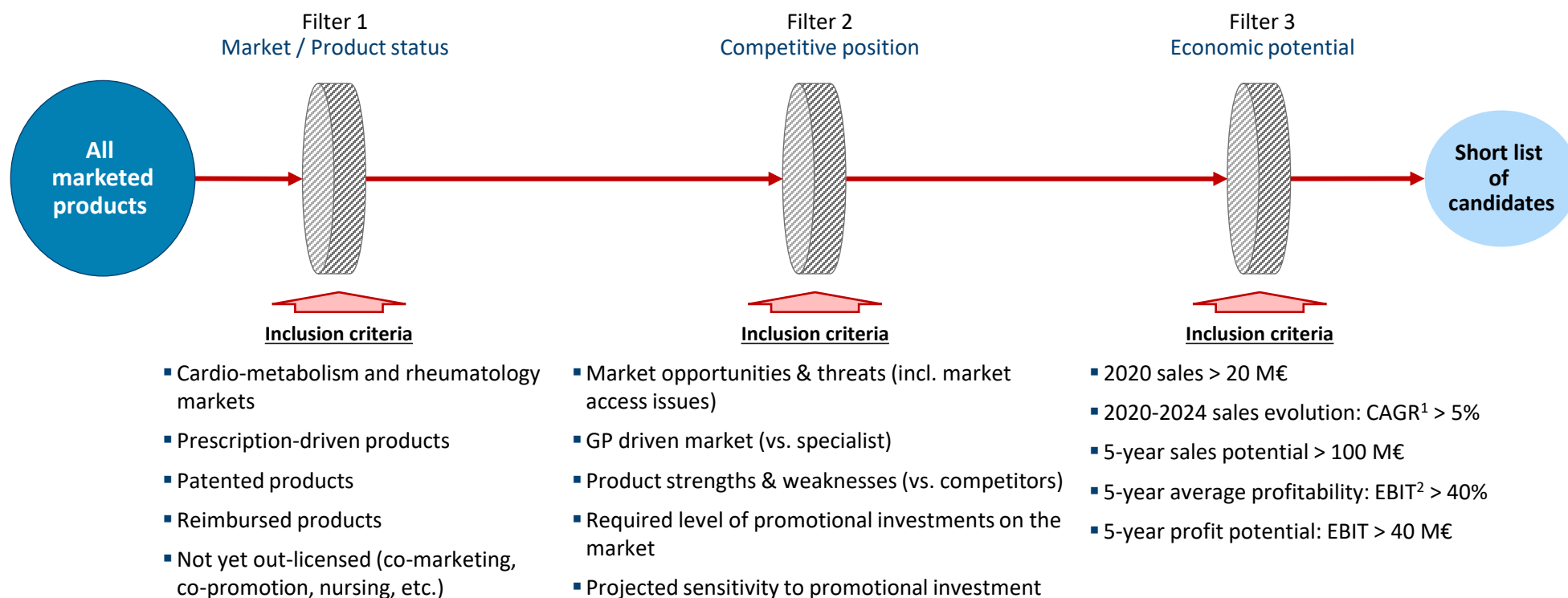


The selection of most attractive candidate products already marketed, within a defined strategic segment, can be established through the following methodology

Marketed product screening

Rx-bound products in France

Illustrative



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

Example of short-listed candidate products

Under development products

Illustrative

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

Marketed products

Molecule	Brand name	Originator	Therapeutic class	Sales 2020	CAGR 2020 -2024 ¹	Sales 2020 -24	Promotional spend (2020)	Profits 2020 -24
Rosuvastatin	CRESTOR	Astra Zeneca	C10A1	162 M€	25%	162 M€	20 M€	142 M€
Pravastatin + aspirin	PRAVADUAL	BMS	C10A1	21 M€	30%	21 M€	5 M€	16 M€
Ezetimibe	EZETROL	Merck&Co	C10A9	75 M€	12%	75 M€	7 M€	68 M€
Ibandronic acid	BONVIVA	Roche	M05B3	32 M€	15%	32 M€	16 M€	16 M€
Eletriptan	RELPAK	Pfizer	N02C1	26 M€	4%	26 M€	6 M€	20 M€
Hydroxyzine	ATARAX	UCB Pharma	N05C	20 M€	2%	20 M€	4 M€	16 M€
Mometasone furoate	NASONEX	Schering - Plough	R01A1	42 M€	5%	42 M€	9 M€	33 M€
Montelukast	SINGULAR	Merck&Co	R03J2	101M€	4%	101 M€	9 M€	92 M€
Levocetirizine	XYZALL	UCB Pharma	R06A	36 M€	-5%	36 M€	11 M€	25 M€


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

Example of identity card for short-listed candidate products













Molecule:-----	Brand name: -----	Originator: -----	Therapeutic class: -----
----------------	-------------------	-------------------	--------------------------

Product attributes

Sales 2020	CAGR ¹ 16-20	Sales 16-20	Promo spend ²	Profits 16-20
-----M€	-----%	-----M€	-----%	-----M€

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

SWOT analysis

Market Opportunities	Market threats
■ -----  ■ -----  ■ ----- 	■ -----  ■ -----  ■ ----- 
Product strengths	Product weaknesses
■ -----  ■ -----  ■ ----- 	■ -----  ■ -----  ■ ----- 

Value for the acquirer	Value for the owner
-----	-----
-----	-----
-----	-----
-----	-----
-----	-----

Recommendations

☒ GO

☐ NO GO

Preferred types of deals

☒ Exclusive marketing license
☐ Non-exclusive marketing license

☒ Co-marketing
☐ Nursing

☐ Co-promotion
☐ Acquisition

☐ Other:-----

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

Key learnings (1/2)

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

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

Key learnings (2/2)

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

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

Smart Pharma Consulting Services

Experiences & competencies in BD&L and Strategic Due Diligences

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

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

Smart Pharma Consulting Services

Masterclass¹: BD&L best practices

Day 1

- 9:00 Introduction (objectives, organization of the day, specific requests from participants)
- 9:15 Lecture / discussion #1: BD&L objective and basic principles
- 10:00 Exercise #1 in plenary session: Would BD&L deals make sense at your affiliate / region level? And why?
- 10:40 Break
- 11:00 Exercise #2 in working groups: Draw the list of relevant information to be collected to evaluate BD&L opportunities, the corresponding sources and their level of reliability
- 11:50 Debrief of the exercise #2 and key takeaways
- 13:00 Lunch
- 14:00 Lecture & discussion #2: Market, product and company data analyses: best practices
- 15:00 Case study #1: Opportunity assessment
 - Group A: Rx-driven product
 - Group B: OTC product
 - Group C: Medical device
- 16:15 Break
- 16:30 Debrief of the case study #1 and key takeaways
- 17:30 Conclusions of the day
- 17:45 End of the session

Day 2

- 9:00 Lecture & discussion #3: Method and Tools to select most attractive opportunities (charts, ID cards, valuation techniques)
- 9:40 Case study #2: Best candidate(s) selection
 - Groups A – B & C
- 11:00 Break
- 11:15 Debrief of the case study #2 and key takeaways
- 12:15 Lecture & discussion #4: Definition of the best deal structure (e.g. in-licensing, JV, acquisition)
- 12:35 Case study #3 in plenary session: Which deal structure to favor according to the situation?
- 13:00 Lunch
- 14:00 Lecture & discussion #5: How to approach and negotiate a BD&L opportunity?
- 14:45 Case study #4: Approach & Negotiation
 - Groups A – B & C
- 15:45 Break
- 16:00 Debrief of the case study #4 and key takeaways
- 16:45 Lecture & discussion #6: Alliance management best practices
- 17:15 Conclusions of the session
- 17:45 End of the session

Patient-centric Strategy

BEST-IN-CLASS SERIES

What patient services pharma
companies should propose

This section proposes guidelines to define a patient-centric strategy and the corresponding initiatives to create value for all stakeholders

Key issues addressed

1. What does patient centricity mean?

2. Why is patient centricity essential?

3. How to craft a patient-centric strategy?

4. How to implement patient-centric initiatives?

“Put patients first and profits will follow” – George W. Merck¹

¹ Adapted from the following quote of George W. Merck, Former President & Chairman of Merck & Co: “We try never to forget that medicine is for the people. It is not for the profits. The profits follow, and if we have remembered that, they have never failed to appear. The better we have remembered it, the larger they have been”

More and more pharma companies have been communicating over the past years that patients are at the heart of their strategy

Is it a buzzword? (1/3)

Illustrative¹


"Our business is focused on making the most meaningful difference to patient health through great medicines"

"We are dedicated to improving the quality of human life by enabling people to do more, feel better and live longer"



"Driven by our commitment to patients, we bring innovative products, services and solutions to people throughout the world"

"We make products and services with the purpose of making a difference and having an impact in people's everyday lives"



"Our mission is to discover new ways to improve and extend people's lives"

"UCB is inspired by patients and driven by science. Patients are at the heart of everything we do"



"Everything we do - from producing pharmaceuticals to offering numerous other relevant services - is patient-driven"

If patient-centricity is a stated priority, it has taken on different meanings and led to different types of projects of variable scope, depending on the pharma companies

Is it a buzzword? (2/3)

- The concept of patient centricity is widely used in the pharma sector and can be defined as:

“Offering solutions (products and/or services) – directly or indirectly – to patients from which they can benefit in terms of medical results and / or quality of life”

- In practice, patient-centric strategies have been materialized in business initiatives very different in nature and importance, ranging:
 - From publishing disease-related documents
 - To involving patients in key decisions all along the life cycle of a drug
 - Via bringing a support along the patient journey with specific services

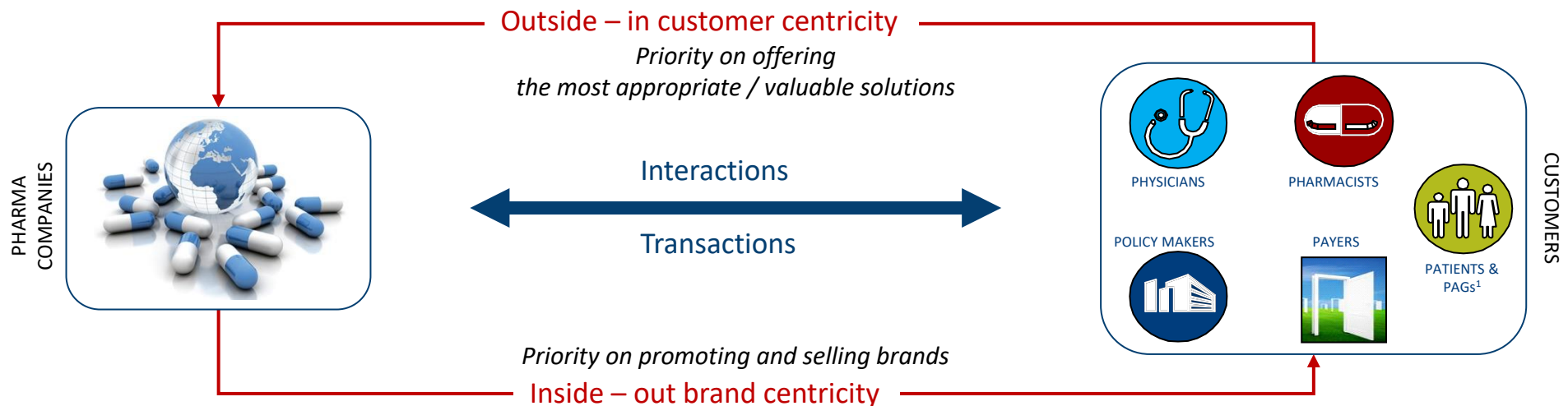


- Patient-centricity should not be just another buzzword because it is relevant for pharma companies:
 - To craft their business strategy, based on the end customers’ needs and wants, i.e., the patients
 - To make sure that patients will get the best medical outcomes and quality of life, considering their disease and the treatment they have been prescribed by physicians and this, along the patient journey

Patient centricity is one component of the customer centricity strategy which consists in going that extra mile to provide entire satisfaction to customers

Is it a buzzword? (3/3)

- Patient centricity is part of the customer centricity concept which has become one of the strategic pharma companies' priorities for a decade or so
- Customer centricity is about building positive experiences with customers through the quality of interactions and/or the benefits provided by products or related services offered by the companies
- Amongst the different customers, patients occupy a particular position in the sense that they are the end customers and as such the customers of all the other stakeholders of the pharma market



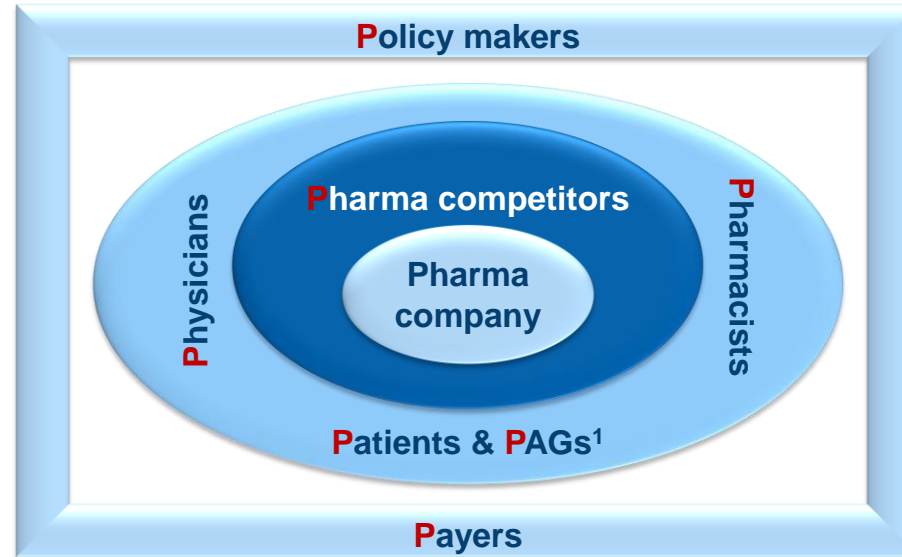
Patients and patients' advocacy groups represent two of the seven key pharma stakeholders groups whose power of influence has recently increased

Importance of patients & PAGs¹ in the pharma business model

Key pharma stakeholder groups: The 7Ps

Patients

- Patients are becoming more aware and knowledgeable (medical information is easily accessible on the Internet)
- Their power is increasing with digital technologies, social networks and the support of PAGs
- Patients are more demanding:
 - They want the most effective and best tolerated drugs...
 - ... that are easy-to-use...
 - ... and available at an affordable price



PAGs

- Patient organizations are also more influential
- They exert a growing power of influence and may be part of the policy-maker / payer decision-making processes
- Thus, PAGs can support pharma companies they have partnered with if they adhere to their strategy
- On the contrary, they can damage the corporate reputation of companies with which they don't have good relationships and with which they don't share the same strategic vision

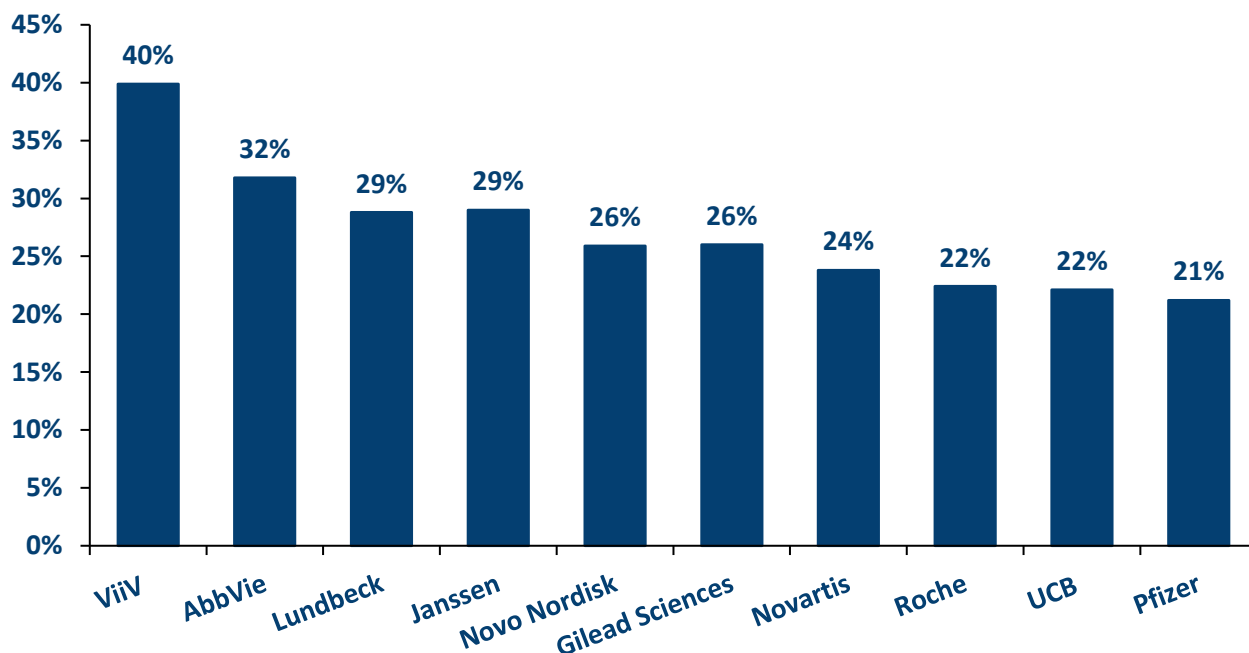
"The patient voice gaining power and reach, it is going to play an increasing role on corporate reputation and will impact the products all along their life cycle"

A recent survey has shown that pharma companies having the best reputation, from the patient perspective, are very active in supporting patient-centric projects

Pharma company reputation assessment by patients

Corporate reputation – Ranking of the 10 performers

Average score¹



ViiV has built strong relationships with patients by funding numerous patient-centric projects to support communities affected by HIV, across the world, especially in Europe and Africa

- The corporate reputation of pharma companies from the patient perspective has been assessed through six indicators:
 1. Patient centricity
 2. Patient information
 3. Patient safety
 4. Usefulness of products
 5. Transparency
 6. Integrity
- Patient groups' opinion is mainly driven by:
 - Number and value of new drugs
 - Post-patent expiry strategy (e.g., pricing, generics defense initiatives, etc.)
 - Mergers & Acquisitions (e.g., financial / tax optimization vs. strategic rationale)
 - Drug pricing and market access
 - Corporate behaviors (e.g., transparency, ethics, etc.)

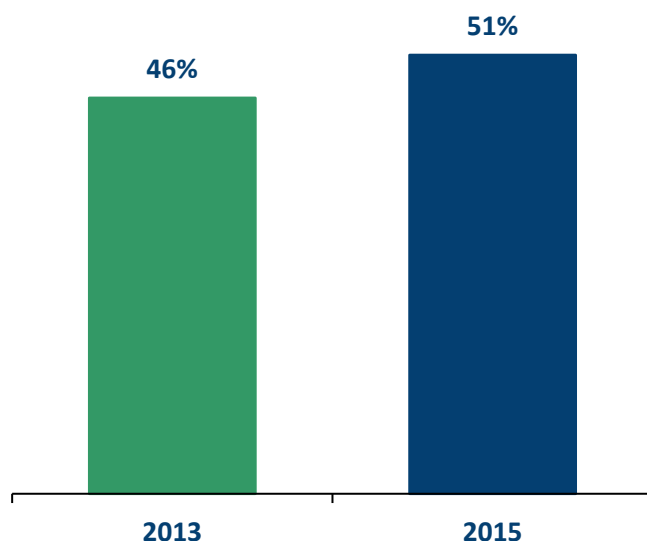
Sources: PatientView 2016 (1,075 patient groups from 72 countries have been interviewed from November 2015 to January 2016 to assess 48 pharma companies)

¹ The average score is obtained by adding and averaging the percentage scores (i.e., percentage of patient groups stating that the company is "best") attained by the companies across the six indicators of corporate reputation

According to pharma companies' executives, patient-centric capabilities are slightly improving while they offer a large variety of patient-centric services

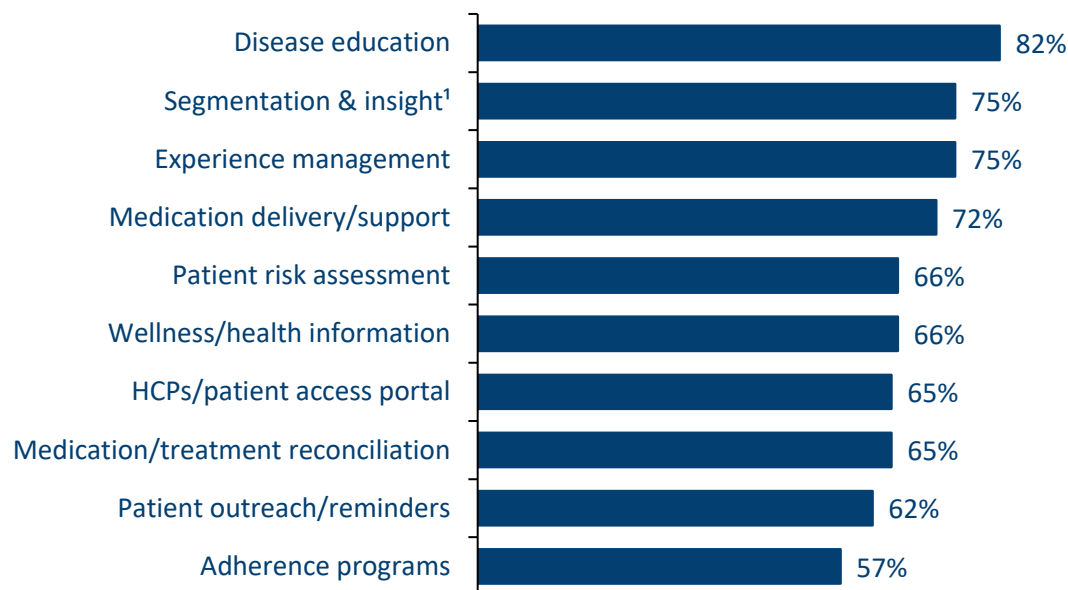
Patient-centricity viewed by pharma companies

Patient-centric capabilities with pharma companies



% of respondents rating capabilities as strong

Top 10 patient-centric services offered by pharma companies

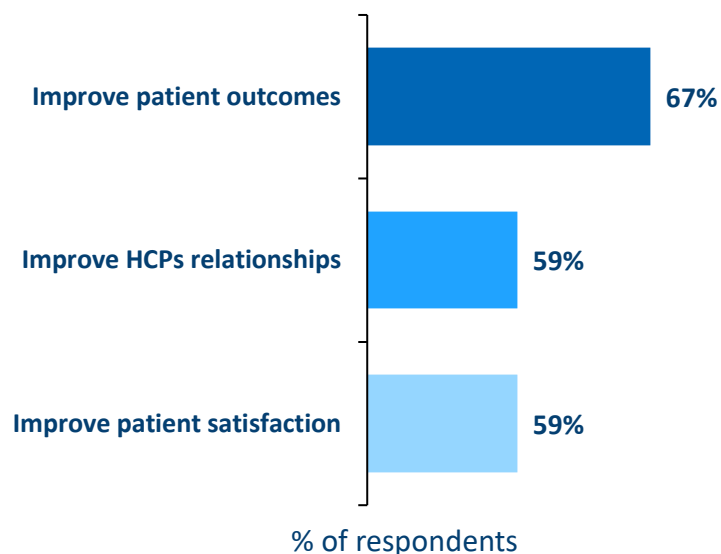


% of respondents having cited these services amongst the top three

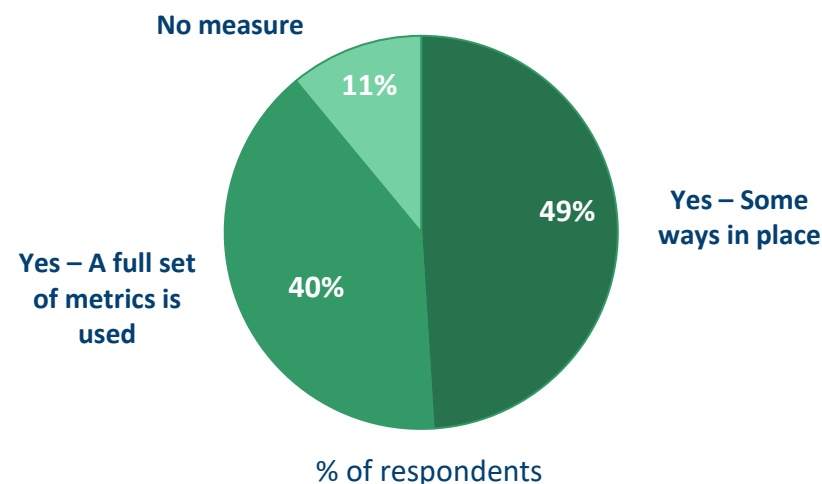
Offering patient services is a good decision, provided these services are used and they demonstrate their positive impact with the help of reliable metrics

Objectives & impact measurement as viewed by pharma companies

What are your objectives in offering patient services?¹



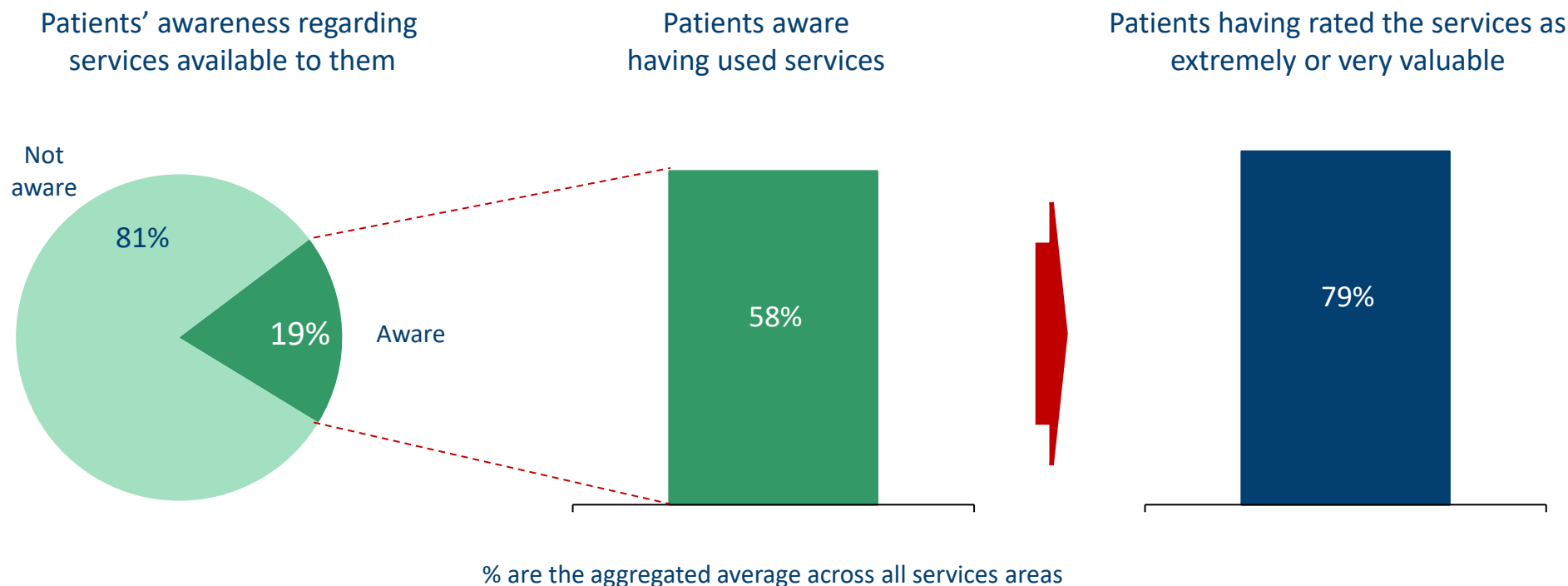
Are you able to measure the impact of these services?¹



- Offering services is a good start, but it is not sufficient
- Pharma companies must prove with tangible and reliable data that the patient services they invest in have a positive impact for the patients and create value, in return, for the company

Patients' awareness regarding services available to help them is low, but when they are aware, they use them and are in general very satisfied

Awareness – Usage – Valuation of patients' services

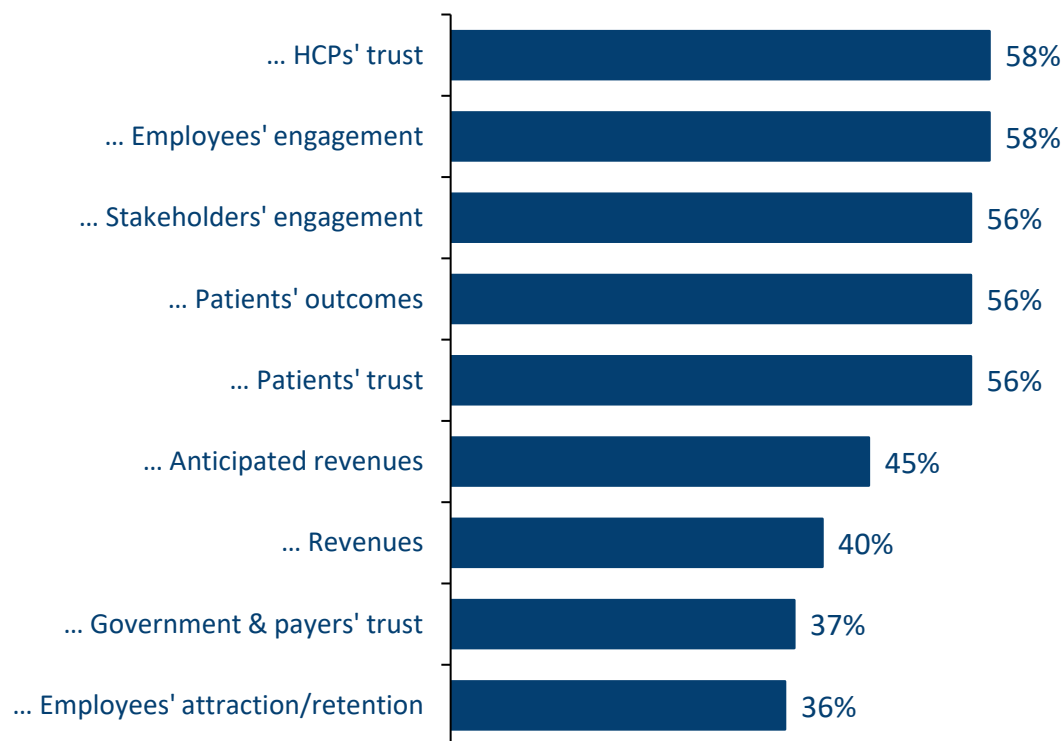


If services are associated with products marketed by pharma companies, they may expect to gain trust and respect amongst the stakeholders (e.g., policy makers, payers, HCPs, PAGs)

There is a growing body of empirical evidence to support the fact that patient-centric initiatives may have a positive impact on pharma companies' profitability

Impact of patient services on pharma companies' profitability

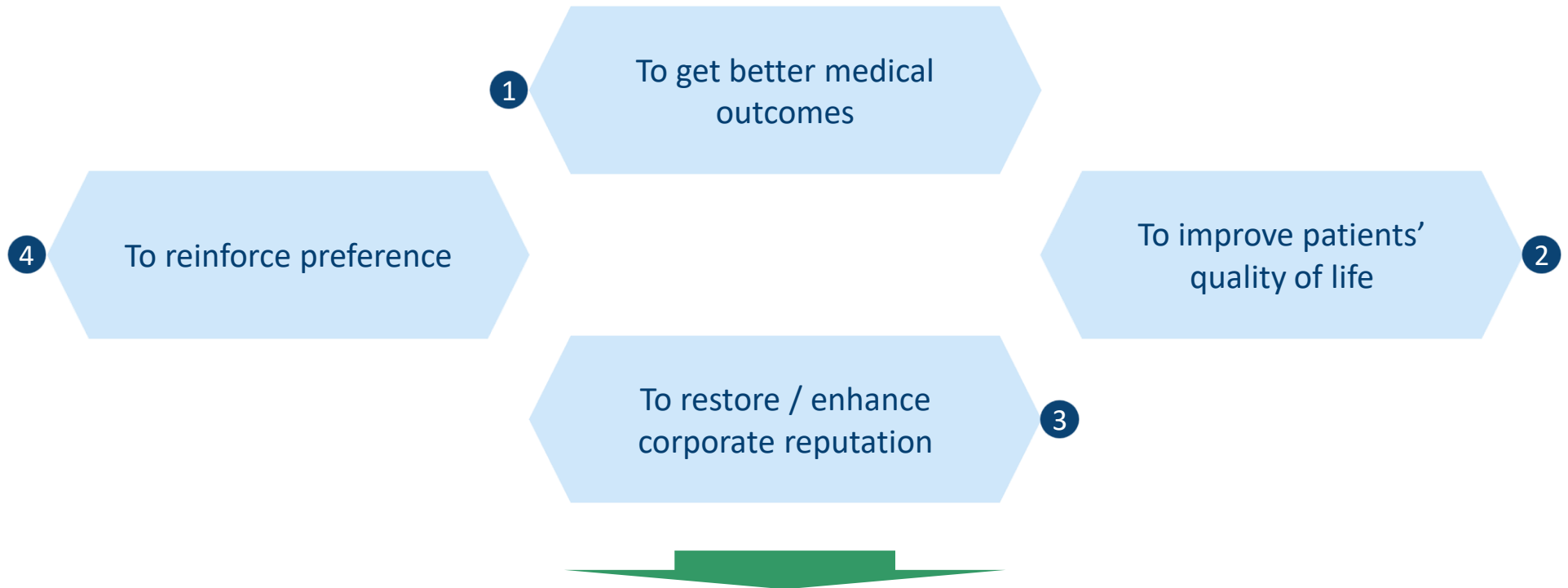
93% of the 2,346 respondents believe that patient-centric strategy improves the overall pharma companies' business outcomes by increasing...



- Patient-centric strategy and the corresponding offered patient services should, in principle, fulfill:
 - Patients' ultimate needs for better health outcomes and improved quality of life
 - Pharma companies' needs for a better usage of its drugs and an increased patient satisfaction leading to an enhanced corporate reputation and a market share gain
 - HCPs' needs to prescribe the most appropriate drugs to their patients with the assurance of having a follow up along the patient journey for better results and safety conditions
- The issue for pharma companies is not anymore to wonder if they should offer patient services...
- ... but to decide which services they want to offer to create the best value for patients, HCPs, policy makers, payers, and ultimately for themselves

Relevant and effective services to patients can contribute to improve the corporate reputation of pharma companies and thus increase stakeholders' preference

The four key objectives of patient services



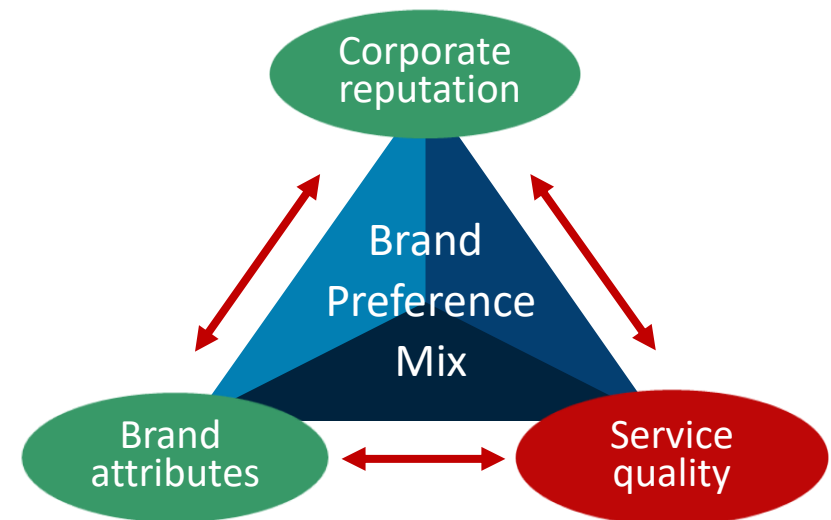
*“Why is the patient so important?
Simply because he is the final customer and, as such, has the last say!”*

With dwindling product differentiation, patient services contribute to strengthen the brand preference of stakeholders (e.g., patients, physicians, policy makers, payers)

Contribution of patient services to brand preference strengthening

*“The more robust is the brand preference
the more exceptional is the brand performance”*

- To strengthen the preference of customers (stakeholders) to their brands, pharma companies must, better than their competitors, optimize the three basic components of the preference mix:
 - Corporate reputation
 - Brand attributes
 - Quality of customer services (incl. patient services)
- Thus, patient services ensuring a more positive patient experience will lead to:
 - Patients’ better medical outcomes and quality of life
 - Physicians’ (and other HCPs¹) increase confidence in the brand
 - Payers’ better value for money
 - Policy makers’ (and government) better fulfilment of their role



*“Offering valuable services to customers
– especially to patients –
reinforces corporate reputation of pharma
companies and preference to their brands”*

Patient services strategy should preferably focus on “around-the-pill” services, likely to strengthen brand preference by improving medical outcomes and quality of life

“Beyond-the-pill” vs. “Around-the-pill” strategy

- While most pharma companies claim to be patient-centric and to offer patient services, they are not very clear, nor aligned on what to do in practice
- Should they provide services “beyond-the-pill” or “around-the-pill”?

Services “beyond-the-pill”

- “Beyond-the-pill” services are not linked to the drugs marketed by pharma companies and therefore have no direct impact on their value, nor on their preference
- They have been imagined as a new source of revenues to compensate the risk associated to drug patent expiries
- Example of services “beyond-the-pill”:
 - Commitment of GSK to reinvest 20%¹ of its profits made in LDCs² and to lower drug prices³
 - Co-development of smart lenses⁴ by Novartis and Google
 - Roche taking majority stake in Foundation Medicine, which develops solutions for genomic profiling of cancers

Services “around-the-pill”

- “Around-the-pill” services can be adjacent or directly linked to drugs marketed by pharma companies
- The purpose of these services is to optimize medical outcomes and patient quality of life while strengthening the preference of the brands marketed by the companies
- Examples of services “around-the-pill”:
 - Trainings/tools to help physicians prescribe the right drug to the right patient
 - Programs/tools to improve adherence to medication
 - Devices to monitor treated patient condition

- Services “beyond-the-pill” correspond to a longer-term strategy for which the business model is not yet clearly set...
- ... while services “around-the-pill” should deliver short-term results through a better usage of marketed drugs

Patient services, as part of pharma companies' customer-centricity strategy, should be focused on initiatives to enhance medical outcomes and quality of life

Examples of “around-the-pill” services

Disease management & progression monitoring



In 2014, Biogen partnered with PatientsLikeMe to distribute Fitbit¹ to 248 multiple sclerosis patients to collect data to help them create improved treatment protocols and prove the value of their medication to payers, physicians and other patients

Connected-device to improve adherence



In 2014, Merck launched a new device to inject Rebif, for patients with multiple sclerosis, which collects and stores data that can then be sent to a secure server. The system can prompt patients to a better **adherence** to treatment

Community web site for lung cancer patients



After completing a patient research survey, AZ co-developed with >100 patients a website dedicated to build a community for lung cancer patients where they can share their emotional journeys and everyday experiences and feel better

Patient support program

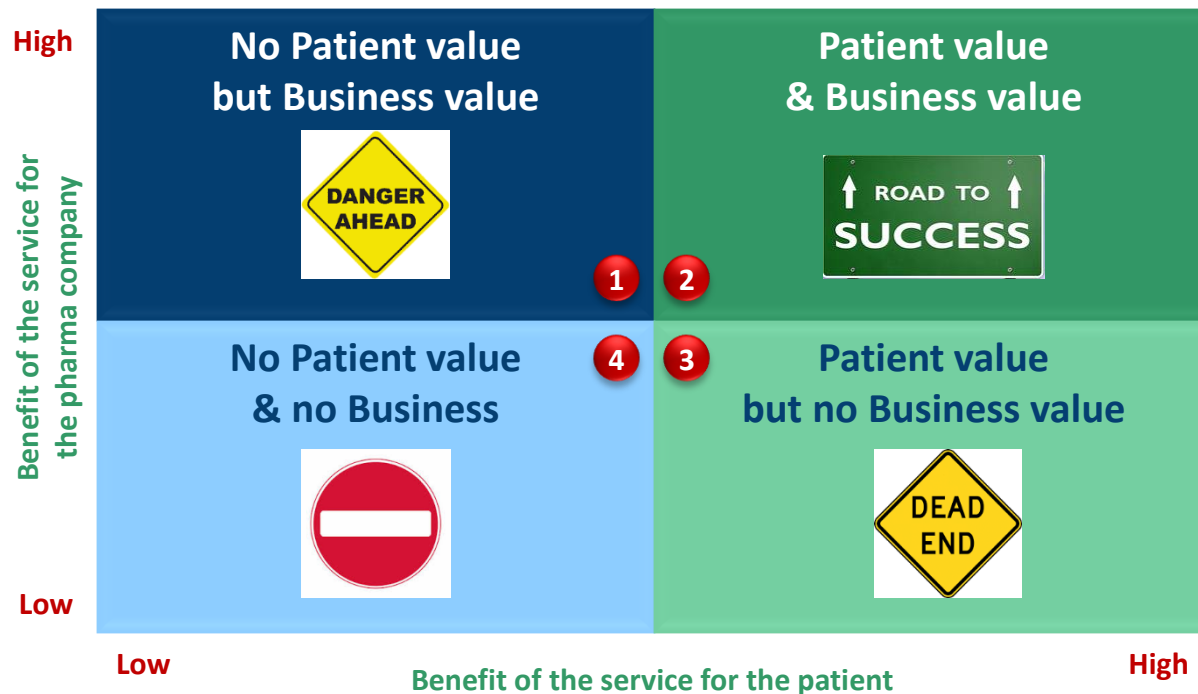


Cornerstones4Care[®] is an online service from Novo Nordisk providing diabetic patients with personalized tools, resources and information to help them reach their diabetic management goals and improve their quality of life

While crafting their strategy, pharma companies should give the priority to services that create tangible value for patients and that contribute to boost their performance

Selection of a patient-centric strategy (1/2)

Patient service strategy matrix



“Patient-centric strategies must improve patients & companies’ outcomes”

- While crafting their patient-centric strategy, pharma companies should keep in mind their ultimate objective:
 - The services which create value for the pharma company but not for the patients (quadrant #1) are not recommended because they represent a short- to mid-term reputational risk for the company
 - The services which create value for both patients and the pharma company (quadrant #2) should be favored because they represent a “win-win” option
 - The services which create value for patients but not for the pharma company (quadrant #3) should either be excluded or redefined if the problem comes from poor implementation
 - The services which do not create value for patients nor for the pharma company (quadrant #4) should be avoided because they are irrelevant

The “win-win” patient-centric strategies proposed by pharma companies should create value for all stakeholders, be perfectly carried out and deliver tangible results

Selection of a patient-centric strategy (2/2)

Features of services delivering value for patients & pharma companies

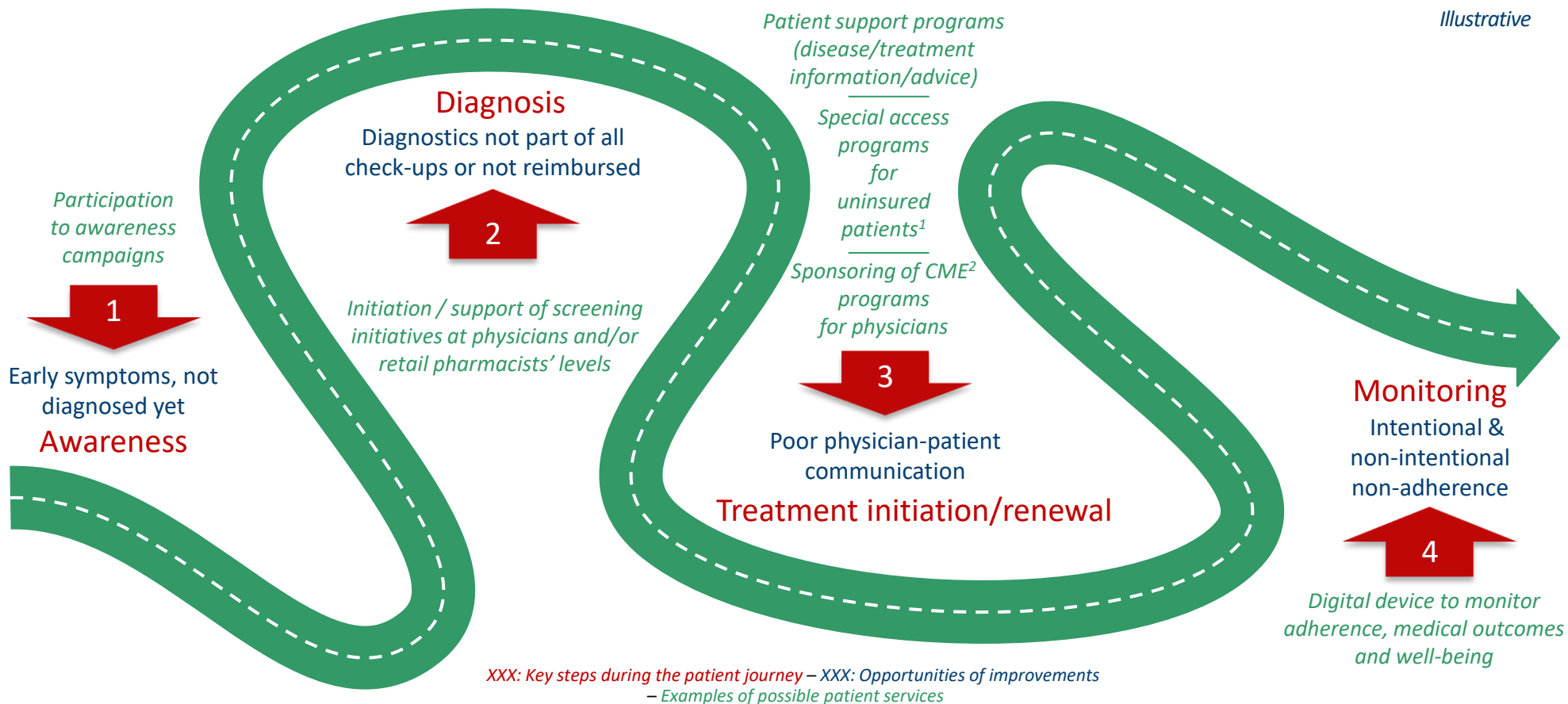
Patient value
& Business value



- The service should correspond to a need expressed by the great majority of patients and acknowledged by the other key customers of the pharma company (i.e., HCPs, policy makers, payers)
- Thus, the patient service must create value for:
 - Patients through better medical outcomes and improved quality of life
 - HCPs through better and easier management of their patients
 - Payers through improved cost-effectiveness results
 - Policy makers / government through improved public health outcomes and management
 - The pharma company by reinforcing its reputation and increasing the preference of stakeholders to its brands
- The service must be reasonably easy to implement¹ and the quality of execution irreproachable
- The expected results on patients must be significant and measurable

Services likely to be proposed to patients by pharma companies can be considered at different steps of the patient journey to address dysfunctions in patient management

Examples of possible patient services along the patient journey






It is key to make sure that the service will create value for patients, other customers and the pharma company, with the help of a specific selecting tool

How to select patient services?

Patient service selecting tool

Illustrative

Targeted patients	Who?	How many?	Objective	For patients		Description of the service		
				For company				
Estimated value ... for Patients			 for HCPs		... for Payers / Policy makers		
Metrics*		Rationale		Metrics*	Rationale	Metrics*	Rationale	
Interest	1 2 3 4 5			1 2 3 4 5		1 2 3 4 5		
Usefulness	1 2 3 4 5			1 2 3 4 5		1 2 3 4 5		
Convenience	1 2 3 4 5			1 2 3 4 5		1 2 3 4 5		
Execution	1 2 3 4 5			1 2 3 4 5		1 2 3 4 5		
Total	1 2 3 4 5			1 2 3 4 5		1 2 3 4 5		
Feasibility		Rationale		Patients KPIs ¹		Company KPIs	Decision	Rationale
Technical		• Implementation		• Biological indicators • Medical outcomes • Quality of Life • MPR ² • Etc.		• Corporate reputation • Brand Preference Mix index • Brand market share • Etc.	GO	
Regulatory		• Compliance					No GO	
Economic		• Estimated cost and return						

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

The successful implementation of patient-centric initiatives requires to adjust the organization, communicate extensively and measure the impact in a rigorous way

Key challenges: Overview

The three challenges to be addressed to successfully implement patient-centric initiatives		
Organization	Communication	Execution & Measurement
<ul style="list-style-type: none"> ▪ Patient-centric initiatives are most often managed by the marketing or medical department... ▪ ... which are not necessarily the optimal options to establish a cross-functional team... ▪ ... which is a “must have” to ensure an effective and efficiency implementation 	<ul style="list-style-type: none"> ▪ 81% of pharma companies go through healthcare providers to make patients aware of their services... ▪ ... 19% of patients are aware of patient services proposed by pharma companies ▪ Patient services may be viewed by stakeholders as a means to sell more drugs by delivering (free) services 	<ul style="list-style-type: none"> ▪ Patient services are often complex and poorly executed ▪ 60% of pharma companies do not measure the impact of their patient services on medical outcomes ▪ In the absence of reliable data and systematic measurement, the investment made will not be valued by stakeholders and... ▪ ... therefore, will not be sustainable

The question is not anymore: “Should we offer patient services”, but “Which ones to offer and how to execute them?”

A patient services department, managed by a senior executive, should be defined to work cross-functionally with other departments to develop high value initiatives

Key challenges: Patient-centric organization (1/2)

Cooperation

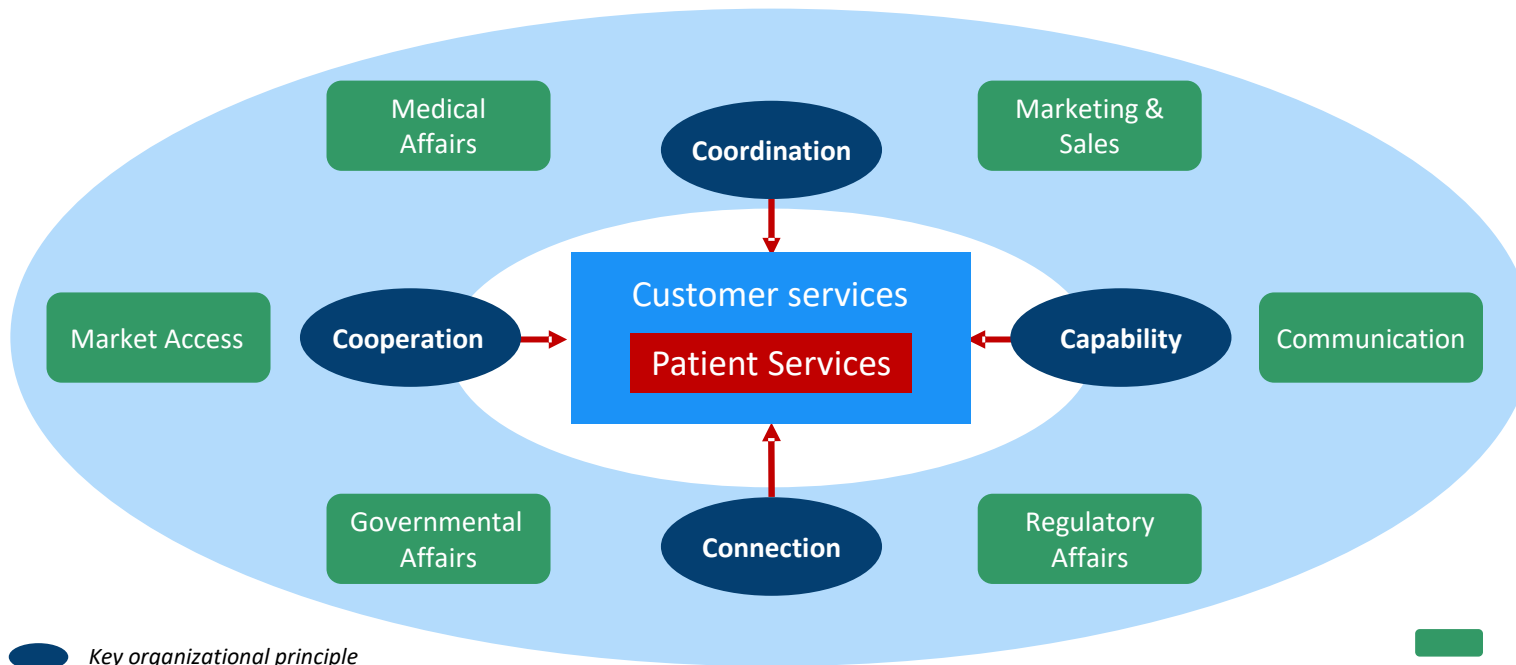
Project teams including members from various departments and centered around patient services

Coordination

- Knowledge- and experience-sharing
- Harmonization of activities

Capability

- Skills to develop and deliver highly valued patient services
- Ability to explore and discover customer insights (deep knowledge of their needs, wants, behaviors)
- Motivated and empowered collaborators



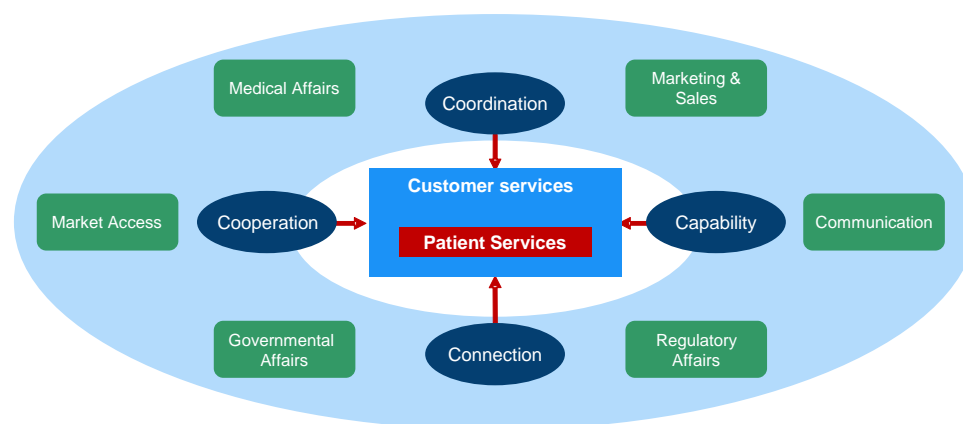
Connection

Partnership with external players to propose unique and highly valued patient services

A customer-centric mindset should be pervasive at every level of the organization, from customer-facing collaborators to the management committee level

Key challenges: Patient-centric organization (2/2)

- A patient-centric organization must be **communicated without any ambiguity** – internally and externally – by the senior management as a long-term strategic priority
- To remain engaged in a patient-centric culture, **collaborators should regularly be kept informed** about the initiatives put in place and their outcomes
- The head of the customer (or patient) service department must be a member of the management committee and **work cross-functionally** with the other key departments heads of the company (e.g., medical, marketing, etc.)
- Besides, collaborators dedicated to patient services must be part of the brand teams to **ensure that the services benefit not only to patients but also to the brand**, directly, or indirectly by reinforcing the corporate reputation
- Irrespective of the department they belong to, of their activities (front vs. back office) or their experience (senior vs. junior position), all collaborators of pharma companies should be committed to deliver **high service quality to customers**, and especially to patients



“Patient services being in general delivered in partnership with other customers of the pharma companies, they require the alignment and coordinated efforts of all departments”

● Key organizational principle

■ Key departments directly involved in customer services / patients' services departments

It is essential for pharma companies to communicate their patient-centric strategy clearly and precisely to internal and external customers, in order to get their support

Key challenges: Communication

Illustrative

- Pharma companies should define and share their vision – mission – ambition related to their customer-centric strategy with their internal (their collaborators) and external customers (their stakeholders)

Vision

- *Being recognized by patients and other customers (HCPs, payers, policy-makers) as the company offering the most valuable patient services*

Mission

- *Improve medical outcomes and quality of life of patients treated with our drugs or affected by a pathology for which we propose drugs*

Ambition

- *Get tangible results demonstrating the value of the patient services and, as a result, increase the preference of stakeholder for our brands*

“Communicate openly about your patient services: What are your intentions? What are the results you obtained? Don’t be afraid, if you do the right things right, your reputation will be strengthened!”

Patient services being complex to execute, skillful collaborators with a robust experience in transversal and project management are required

Key challenges: Execution & Measurement (1/2)

Patient service execution

- **Challenge #1:** Engage HCPs, payers and policy makers, as appropriate, to execute the patient services
- **Challenge #2:** Make patients aware of the services offering and of the benefits they will get
- **Challenge #3:** Keep patients as users and other relevant customers¹, as partners (e.g., HCPs may recommend a website, enroll patients in adherence programs, track the clinical outcomes, etc.) engaged over the long run in the service
- **Challenge #4:** Collect reliable data, on a regular basis, to be able to objectivize the value brought by services to patients, other customers¹, and to the pharma company
- **Challenge #5:** Collaborate with many partners, internally (from different departments) and externally (social networks, data integrators, apps developers, HCPs, etc.) to deliver the service
- **Challenge #6:** Position the patient services to avoid head-to-head competition
- **Challenge #7:** Execute the service to create superior value than competitors, in a context of commoditization of patient services

Rigorous measurement of relevance, quality of execution and outcomes of patient services are essential to objectivize the value created for stakeholders

Key challenges: Execution & Measurement (2/2)

Patient service measurement tool

Targeted patients	Who?	How many?	Objective	For patients	Description of the service			
				For company				
Customers valuation						Pharma company self-valuation		
Metrics*	Patients	HCPs	Payers / Policy makers	Rationale	Metrics*	Rationale		
Interest	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5		1 2 3 4 5			
Usefulness	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5		1 2 3 4 5			
Convenience	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5		1 2 3 4 5			
Execution	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5		1 2 3 4 5			
Total	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5		1 2 3 4 5			
Patients KPIs ¹		Gap analysis	Recommendations	Company KPIs ¹			Gap analysis	Recommendations
Metrics	O ²			A ³	Metrics	O ²		

¹ Key performance indicators – ² Objective – ³ Achievement

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

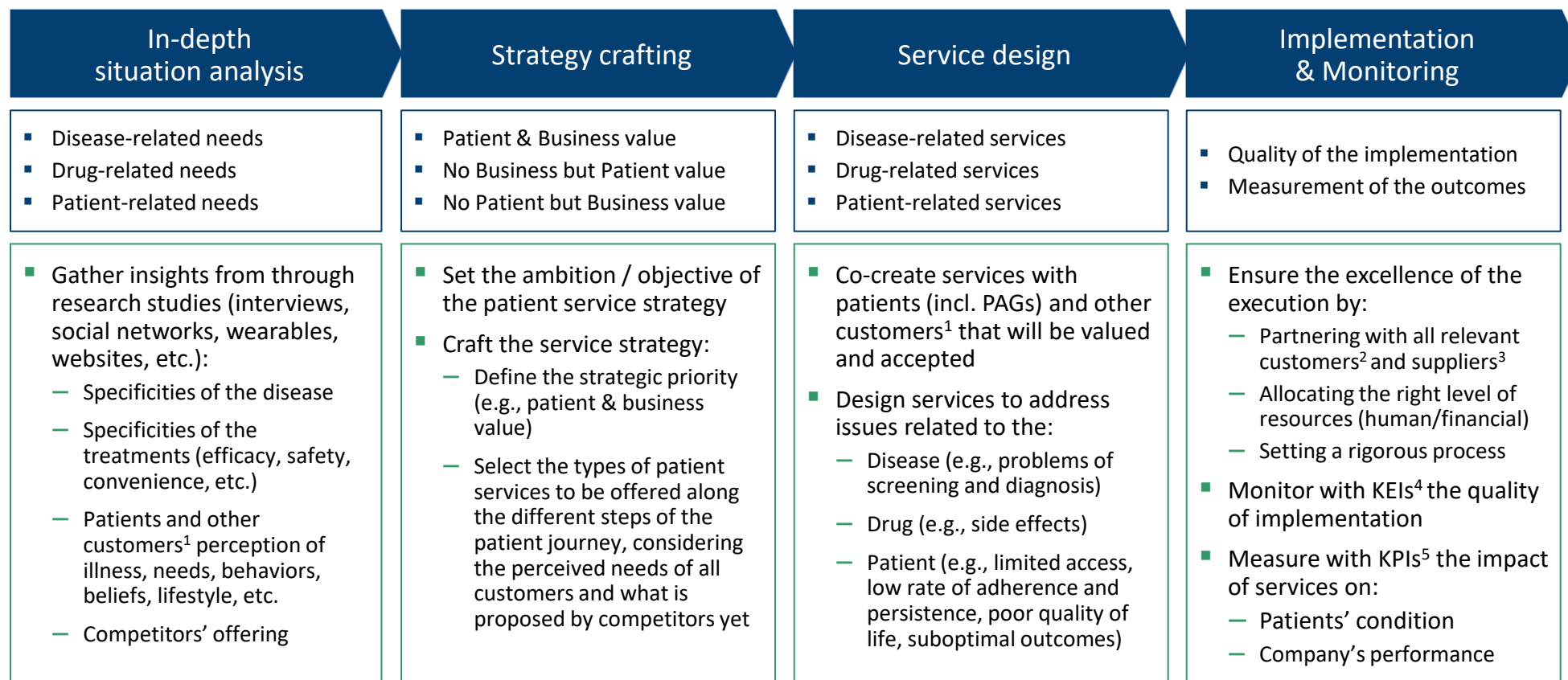
“If you can’t measure it, you can’t manage it”

– Peter Drucker –

- To objectivize the value created by patient services, for the different customers and the pharma company, it is recommended to combine qualitative and quantitative metrics to measure the quality of execution and the impact of the initiatives:
 - Interest and usefulness metrics to assess the relevance of the service
 - Convenience and execution metrics to assess the quality of implementation of the service
 - Patients’ key performance indicators (KPIs) include metrics such as: medical outcomes, quality of life, adherence and persistence rates
 - Pharma key performance indicators include metrics such as: corporate reputation, Brand Preference Mix Index¹, market share dynamics
- The performance gaps (between objectives and achievement) should be carefully analyzed and lead to specific decisions (i.e., adjustment of the execution, drop-out, continuation)

Smart Pharma Consulting proposes a four-step process to define and implement a patient-centric strategy likely to create a sustainable competitive advantage

Strategic patient service process

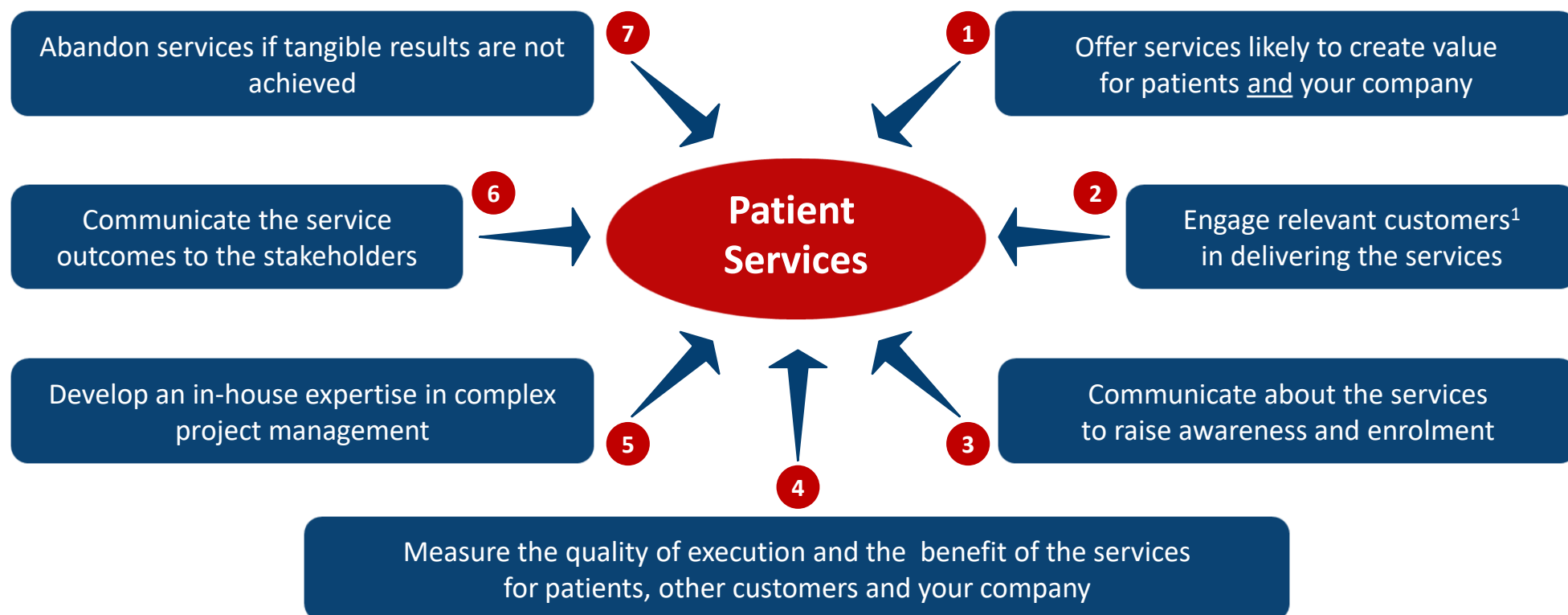


Sources: Adapted and enriched by Smart Pharma Consulting from Executiveinsight

¹ HCPs, payers, policy makers – ² PAGs, HCPs, payers, policy makers, caregivers, etc., depending on the service to be proposed – ³ IT companies, data integrators, E-health agencies, etc. – ⁴ Key execution indicators – ⁵ Key performance indicators

Patient services must deliver significant and concrete results to get stakeholders' esteem and therefore enhance their preference for the pharma company and its drugs

7 tips to create and implement a patient-centric strategy



"The right patient-centric strategy maintain a proper balance between the patient and the pharma company interests"

Smart Pharma Consulting can help you strengthen the impact of your patient-centric strategy by stimulating your thinking process and bringing specific methods and tools

5 ways Smart Pharma Consulting can boost your patient-centric strategy



How can Creativity Boost Performance?

BEST-IN-CLASS SERIES

Application to
pharma companies

*“The true sign of intelligence is not in
knowledge but imagination”*

Albert Einstein

Pharma companies are facing a paradigm shift which forces them to reinvent in a creative way their strategy, the corresponding tactics and their organization

Context – Objective – Approach

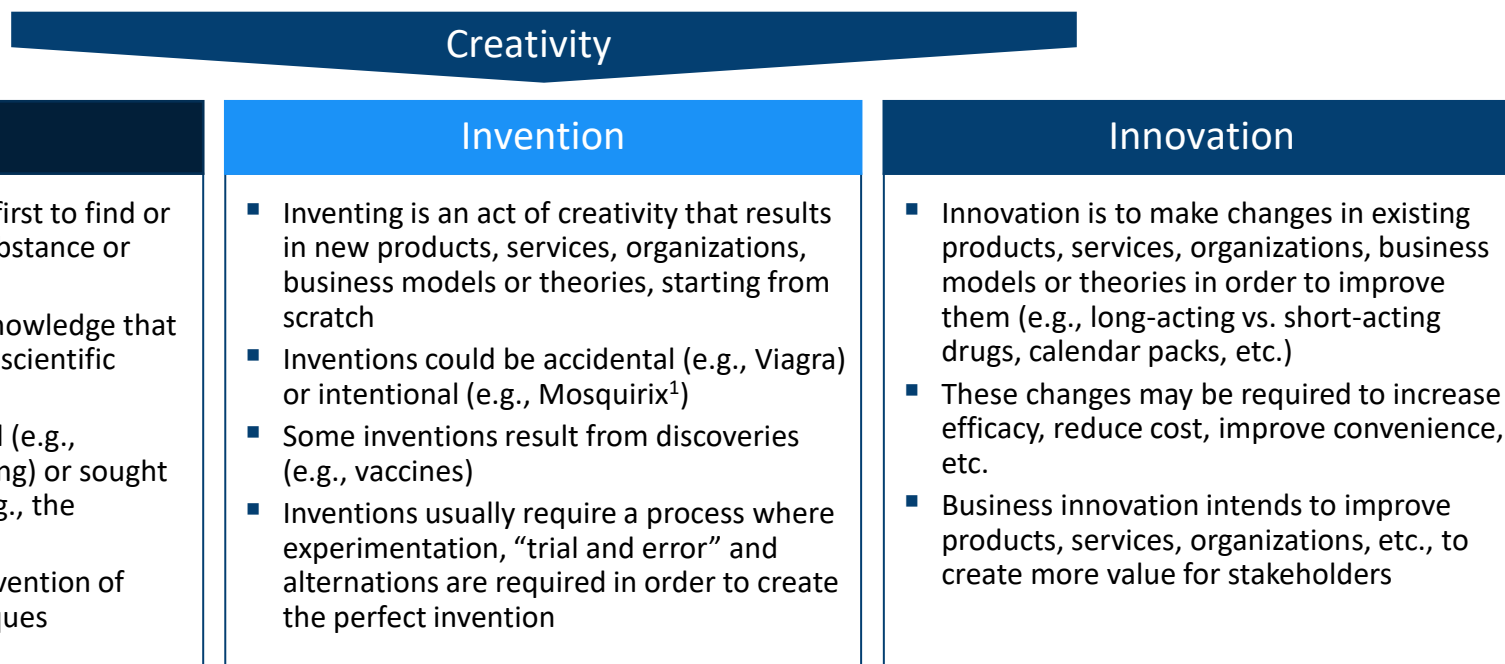
- Pharmaceutical companies must urgently **rethink creatively** their business model to face the **paradigm shift** that is occurring:
 - Health authorities keep on raising **barriers** regarding drug **registration** and **marketing conditions**
 - **Payers** have no choice but to put more **pressure on drug price**, including on innovative ones
 - **Healthcare professionals** tend to **reduce** their number of **interactions** and to become less and **less sensitive to promotion**
- To help pharma companies figure out how to leverage creativity to boost their performance, Smart Pharma Consulting will attempt to answer the following questions:
 - **Why is creativity so important?**
 - **How to craft a creative strategy?**
 - **How to build a creativity-driven organization?**

“We are continually faced with great opportunities, brilliantly disguised as insoluble problems” – John W. Gardner

In the business context, creativity stimulates discoveries, inventions and innovations that could potentially result in highly valuable products, services, organizations, etc.

Role of creativity in business

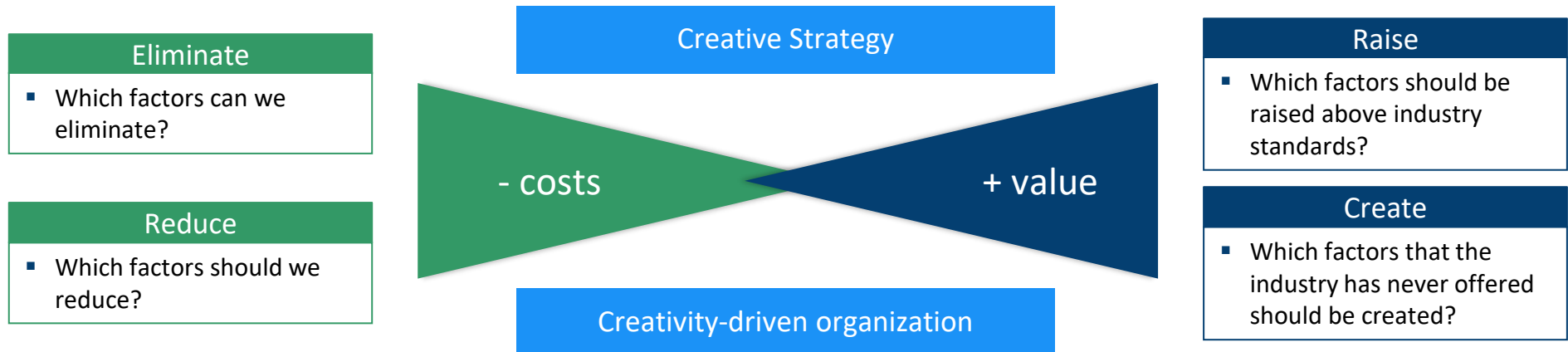
- Creativity is the development of ideas about products, services, organizations, business models or theories that are novel and potentially valuable
- Creativity involves the ability to break down and restructure conventional knowledge to produce different viewpoints and insights
- Creativity can potentially lead to various discoveries, inventions and innovations



To cope with a deteriorating competitive environment, pharma companies must build a creative business model to reduce costs and/or offer better value to customers

New pharma business model

- The new business model that pharma companies must craft should simultaneously:
 - Reduce costs by eliminating less valuable features or services
 - Increase customer value (and in return company value) by offering new benefits and services
 - Rethink the organization so that functional and operational activities be fully aligned to support the associated strategy

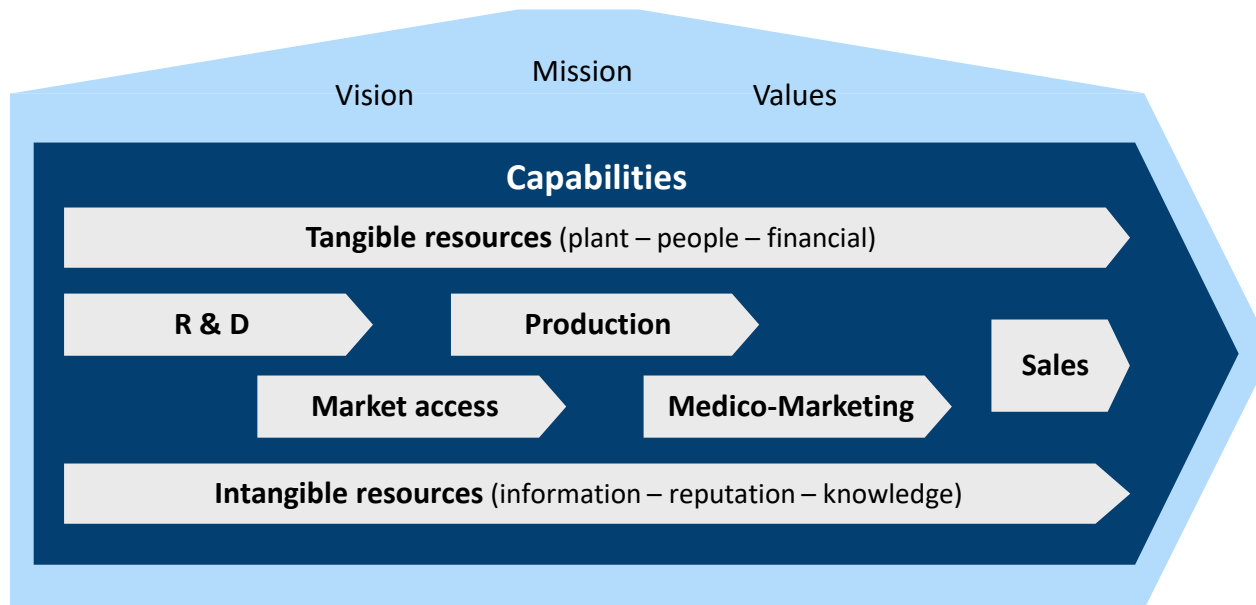


*"New business models consist in doing things differently...
... while new business strategies consist in doing different things"*

To craft a successful creative strategy, pharma companies must identify the business opportunities where they could have the strongest competitive advantage

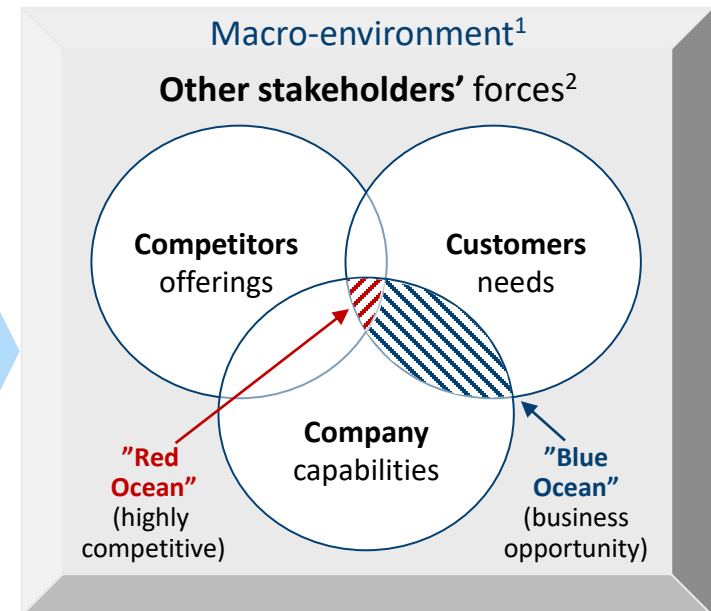
Creative strategy crafting (1/3)

Company's business model



Strengths & Weaknesses
(Competitive advantage)

Strategic segments



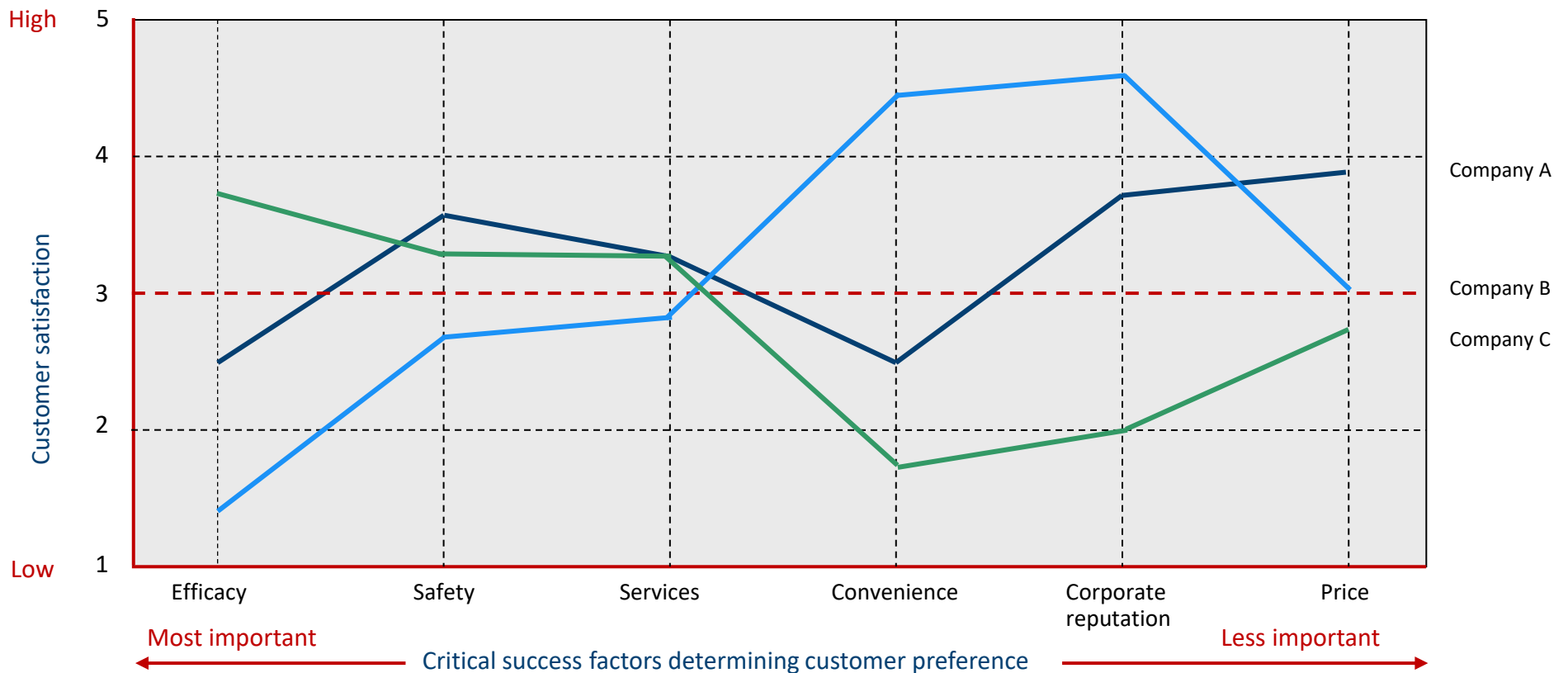
Opportunities & Threats
(Attractiveness & Key success factors)

Ambition & Strategic priorities

The Strategic Canvas is both a diagnostic tool to identify gaps not fully exploited by competition and a decision-aid to select which ones to fill up, to meet customer needs

Creative strategy crafting (2/3)

Strategic Canvas (Value curves)



Sources: Adapted after C. Kim et R. Mauborgne 2005

“Blue Ocean” strategies, based on value innovation, consist in creating new market spaces, making the competition either “irrelevant” or weak

Creative strategy crafting (3/3)

New market space conception

Red Ocean Strategy

1. Compete in the existing market space
2. Beat the competition
3. Exploit the existing demand
4. Make the value-cost trade off
5. Align the organization with its differentiation or low-cost strategy

Structuralist approach

Blue Ocean Strategy

1. Create an uncontested market space
2. Make the competition irrelevant
3. Create & capture new demand
4. Break the value-cost trade off
5. Align the organization in pursuit of differentiation and low-cost strategy

Reconstructionist approach

“Develop a strategy that structures the market and not a strategy that adjusts to the market structure”

To exploit new business opportunities, companies must develop new strategies consisting in doing different things that will be highly valued by customers

“Blue Ocean” strategic examples

Price & Performance

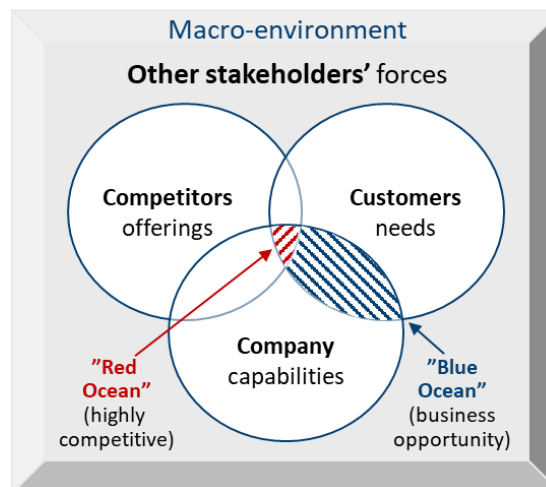


Since 2009, GSK is committed to reinvest 20%¹ of profits made in LDCs² and to heavily lower drug prices³ to increase patient access and then grow on a strategic segment disregarded by most of big pharma companies

Around-the-pill services



In 2014, Merck launched a device to inject Rebif, for patients with MS⁴, which collects and stores data that can then be sent to a secure server. The system can prompt patients to a better adherence to treatment



Functional vs. Emotional focus

Viagra was not positioned by Pfizer as a treatment of erectile dysfunction but as a solution to enhance patients' life-style, putting the emphasis on emotional appeal



Physicians vs. Patients focus



NovoPen, the first insulin pen injector, was introduced in 1985 by Novo Nordisk, to make injection more convenient and easier for patients, improving their quality of life and their adherence to treatment

The creative power of individuals is based on four key dimensions that vary significantly according to innate and acquired personality of individuals

Key traits of creative individuals

Originality

- They can spot underlying patterns in events
- They produce unique, novel, new, creative or innovative and unusual ideas

Flexibility

- They can shift from one approach to another when addressing issues
- They see relationships between seemingly disconnected elements
- They produce a large variety of ideas

Fluency

- They can produce many ideas
- They cope with paradoxes
- They challenge status quo
- They can mix viewpoints or perspectives

Proactivity

- They are curious
- They look beyond the first “right idea”
- They are not afraid to make mistakes
- They take risks

“Chance favors only the prepared mind” – Louis Pasteur

To free the creative power of individuals, these barriers must be lowered or removed, and a free-wheeling atmosphere generated in which all ideas are acceptable

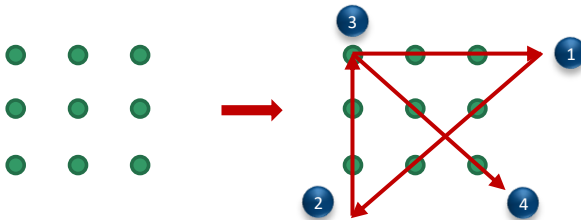
Creativity barrier removal (1/2)

Self-imposed barriers

- Self-imposed barriers are put either consciously or unconsciously
- They are difficult to recognize...
- ... but easy to remove, once they have been recognized

Illustration

Join the nine dots with four straight lines without taking the pencil off the paper

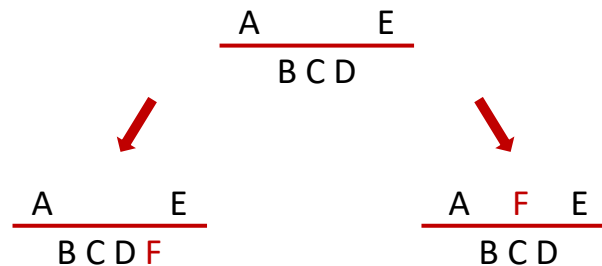


Conventional pattern

- Analytical thinking seeks to establish a conventional pattern to find one solution
- However, several patterns may exist and thus several possible solutions to address an issue

Illustration

Add F to the following letters¹:



Absence of challenge

- Tendency to go for the obvious answer which will be accepted without any question
- However, some other, and possible better solutions, may exist

Illustration

What is the capital of South Africa²?

How to enter the French generic market?
(through acquisition or from scratch by adopting an innovative business model)

How to agree on drug price with payers?
(through conventional price/volume deals or path-breaking value-based models)

To free the creative power of individuals, these barriers must be lowered or removed, and a free-wheeling atmosphere generated in which all ideas are acceptable

Creativity barrier removal (2/2)

Too quick evaluation

- This barrier is difficult to remove
- Some people tend to evaluate and reject ideas that are offbeat or new
- Thus, new or original ideas risk to be dismissed right away

Illustration

Replace the static 2-D segmentation matrix by the dynamic 3-D matrix¹

Develop innovative ideas to create “high impact interactions” between physicians and medical representatives²

Adopt the Brand Preference Mix instead of the 4 Ps of the Marketing Mix³

Fear of looking like a fool

- People do not like going against universally accepted views by fear of being wrong and laughed at
- However, a great deal of inventors have taken the risk to challenge the mainstream thought

Illustration

With his equating mass and energy as different forms of the same phenomenon $E=mc^2$, Albert Einstein broke the rules of Newtonian physics

The Polish astronomer Nicolaus Copernicus was the first astronomer to formulate a scientifically-based heliocentric cosmology that displaced the Earth from the center of the universe

***“To live a creative life,
we must lose our fear of
being wrong” – Joseph C. Pierce***

The mental attitude of individuals can be modified to stimulate the generation of new ideas by applying simple rules

Creativity stimulation: Practical rules (1/2)

Connect unrelated ideas or things

(e.g., In the 17th century, the German astronomer Johannes Kepler drew attention to the fact that tides are somehow linked to the movement of the Moon¹)

Search for new applications

(e.g., A visual analogue scale designed to assess the pain of patients may as well be used to assess patients' well-being)

See things in different ways

One thing may be seen in different ways as shown by this picture



Use metaphors

The metaphor which connects two different universes of meaning through similarities helps understand one idea by another one
(e.g., Thinking of how to catch a fish in order to find new ideas to attract more customers)

Cultivate a sense of humor

Both Albert Einstein and Leonardo da Vinci cultivated the humorous perspective
*(e.g., How deep is the ocean?
Just a stone's throw)*

“The metaphor is probably the most fertile power possessed by man” – José Ortega y Gasset

The mental attitude of individuals can be modified to stimulate the generation of new ideas by applying simple rules

Creativity stimulation: Practical rules (2/2)

Get rid of excuses

It takes more creativity to get rid of excuses than it does to produce new ideas
(e.g., When the Spanish conquistador Hernan Cortés, arrived at Veracruz in Mexico, he burned his ships and told his men “Now you can either fight or die”. Thus, removing the possibility to give up and return to Spain)

Think ambiguously

If ambiguity causes confusion and communication problems, it can also be a powerful stimulant to imagination

Reverse viewpoints

By turning conventional logic upside down, we may generate new ideas, and thus open our thinking
(e.g., Noting that milkmaids were generally immune to smallpox, Edward A. Jenner postulated that the pus in the blisters that milkmaids received from cowpox - a disease like smallpox, but much less virulent - protected them from smallpox. Then Jenner tested his hypothesis by inoculating people and proved that they were immune to smallpox). Jenner developed and generalized the vaccination technique)

Be persistent

It is important to be persistent when attacking creatively a problem and to keep on searching even when you feel like giving up

Search for alternatives (Knight's move thinking)

Replace the “either/or” statement by “How to” to find additional options
(e.g., Either you drop your price or lose your customer. The question: “How to retain the customer?” can help find new options)

“Creativity is contagious. Pass it on” – Albert Einstein


Creativity-spurring checklists help open minds and explore new areas to find creative ideas by stimulating imagination

Creativity stimulation: Idea-generating techniques (1/4)

SCAMPER		
S	Substitute	<i>What could be substituted to make an improvement?</i>
C	Combine	<i>What could be combined to make something more useful?</i>
A	Adapt	<i>How could the product or service be adjusted for a better output?</i>
M	Modify	<i>What could be modified, minified or magnified?</i>
P	Put to other uses	<i>Could the product or service be used in another market?</i>
E	Eliminate	<i>What would happen if a component was removed?</i>
R	Rearrange	<i>Is there something that could be reversed or done in a different order?</i>

Kipling's Questions

The Kipling method is one of the most basic way to explore any idea or problem consisting of a list of 6 fundamental questions



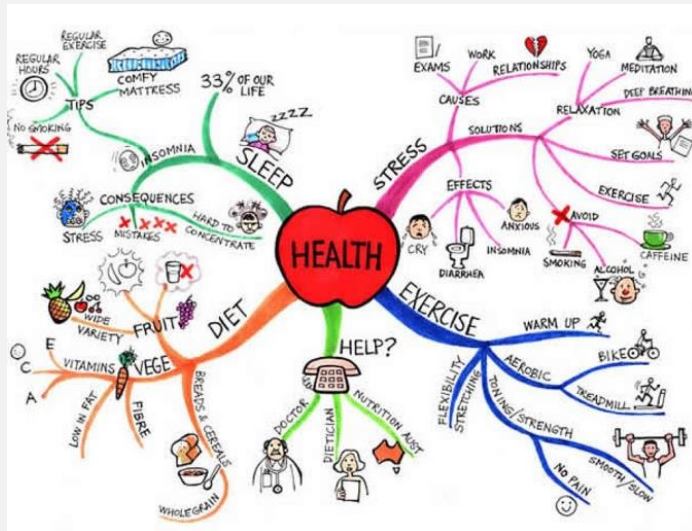
“Questions are the creative acts of intelligence” – Francis Kingdon-Ward

The mind mapping and the relevance tree enable to link thoughts without squeezing them into less natural listing or step-by-step sequence

Creativity stimulation: Idea-generating techniques (2/4)

Description

A mind map is basically a diagram that connects information around a central subject



The relevance tree

The relevance tree serves as visual illustration to help understanding and to stimulate ideas

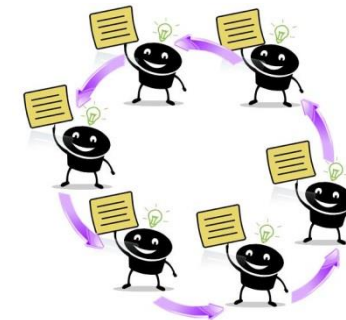


“Creativity is the power to connect the seemingly unconnected” – William Plomer

Creativity stimulation: Idea-generating techniques (3/4)

Brainwriting

- 1 After the **first idea** has been **written** by one of the participants and **passed on** to another, everyone **reacts** – still **through writing** – to the last idea proposed **until no more idea comes out**



- 2 Then, a **list of all the ideas** is given out to each of the participants

"The fusion of knowledge is the most creative act of the human mind" – Elwood Murray

The creativity is stimulated by “synectics” through metaphors and analogies while the “six thinking hats” approach is based on participants role playing

Creativity stimulation: Idea-generating techniques (4/4)

Synectics

“Synectics” combines elements apparently irrelevant by using **metaphors** and drawing **analogies**







The process includes 3 steps:

- **Referring:** Specific problem definition
- **Reflecting:** Imaginative manipulation of the problem, exploring alternatives, possible solutions and translations of various types
- **Reconstruction:** Reinventing or transforming with synectic trigger mechanisms

Add	Transfer	Substitute	Analogize
Subtract	Emphasize	Fragment	Hybridize
Repeat	Animate	Isolate	Disguise
Combine	Parody	Distort	Fantasize

Six thinking hats

Each participant (Thinking Hat) of the creative session has a **specific** color representing an **attitude** (role play) leading to **parallel thinking**:

-  Neutral, objective (facts and figures)
-  Emotional (intuitions, impressions, feelings)
-  Objective, negative (critical, pessimism)
-  Objective positive (optimism, exploration)
-  New ideas (creativity, lateral thinking)
-  Moderator (control, organization, facilitation)

The problem is introduced at the beginning of the meeting and then **everyone** should use **all the hats**

This method provides a **comprehensive understanding** of the **issue** but is time consuming

“You see things; and you say, ‘Why?’ But I dream things that never were; and I say, ‘Why not?’” – George Bernard Shaw

**While the creative thinking enables the generation of many ideas,
the latter should then be evaluated and selected through an analytical thinking process**

Combination of creative and analytical processes

Creative thinking

- Creative thinking (also called lateral thinking) is:
 - Imaginative
 - Divergent
 - Giving many ideas (including those that could be viewed as wild or foolish, and those that appear not to be linked with the problem)

Analytical thinking

- Analytical thinking (also called vertical thinking) is:
 - Logical
 - Convergent
 - Giving a unique or small number of ideas
- This approach requires deep and narrow probing to identify all aspects

Analytical and creative thinking processes
are complement and equally important

Many ideas generated

Few solutions selected

“The creative process is any thinking process which solves a problem in an original and useful way” – H. Herbert Fox

The creativity at various levels of the company can be fostered by the following key recommendations

Key drivers to develop a culture of creativity

1. Provide objective

- Collaborators must have a purpose and direction for their creativity
- Guidelines and reasonable constraints will enable to ensure some control over time and cost

2. Permit more interactions

- Creative climate is stimulated if individuals take part in project and working groups
- Such interactions encourage exchange of information, flow of ideas and fresh perspectives

3. Encourage new ideas

- Throughout the company, new ideas should be encouraged
- Thus, managers should be willing to listen to suggestions, and organize whenever relevant idea generation meetings

4. Tolerate failure

- Most of new ideas will prove to be impractical or useless
- It is however important to invest in experimenting with these new ideas to identify the ones which will be effective

5. Acceptance of change

- Collaborators should ideally participate in making decisions
- Issues like job security should be carefully handled when changes are planned and implemented

6. Offer recognition

- Creative individuals are most often self-motivated
- However, a monetary and/or non-monetary reward should be granted to demonstrate that creative behavior is valued

Creative companies foresee needs that customers have not yet realized and seize opportunities that competitors have not yet seen or have overlooked

Key learnings

- Creativity is a powerful engine to discover, invent and innovate in products, services, processes, concepts, etc., that can potentially boost the performance of companies
- In a deleterious environment, in which innovation is more and more costly, competition intensifies, and payers keep on increasing their pressure on price, pharma companies should put creativity at the top of their agenda to simultaneously:
 - Reduce their costs and increase their value proposition to optimize the performance of their current business
 - Craft innovative “Blue Ocean” strategies to create and develop market spaces in which competition does not yet exist or is still weak
- For so doing, pharma companies should put in place a creativity-driven organization in which:
 - Individual creativity is encouraged and rewarded
 - Group creativity is favored through the introduction of a formal creative thinking process

“Creativity is inventing, experimenting, growing, taking risks, breaking rules, making mistakes, and having fun” – Mary Lou Cook

3. Market Access



Smart Pharma
CONSULTING

Serving & Sharing with Passion

Drug Value & Access Optimization

— BUSINESS REPORT —

From drug cost
to payer valuation

EXCERPTS

Drug Value & Access Optimization

BUSINESS REPORT

From drug cost
to payer valuation

The purpose of this position paper¹ is to provide key information and robust analyses to better optimize drug valuation, from the pharmaceutical companies' perspective

Context & Objective

- To slowdown the increase of healthcare expenditure, governments and public or private payers implement a large array of cost-containment mechanisms
- Drugs are particularly affected by these measures, which include:
 - Drug prices control and regulations to favor the prescription of cheaper products like generics and biosimilars
 - Capping of the prescribed volumes
 - Selective reimbursement of drugs (e.g., limitation to a subset of patients or to the most severe cases)
- However, the way these measures are applied does not allow governments and payers to guarantee access to innovation to the largest number of patients
- Thus, governments and payers have no choice but to increase their pressure on drug prices and “force” pharma companies to accept affordable prices
- In this context, the following questions must be raised:
 - What is the value of innovative drugs for the community?
 - What is a fair price for pharmaceutical companies?
- This report¹ reviews:
 - The economic and healthcare environment
 - The R&D cost of drugs
 - The drug pricing strategic approaches of pharma companies, governments and payers
 - The health economic evaluation methods
 - The market access processes in selected countries
 - The best practices in market access
 - The ways to leverage the corporate reputation of pharma companies
- Smart Pharma Consulting proposes new thoughts likely to help pharma companies to optimize the valuation of their drugs

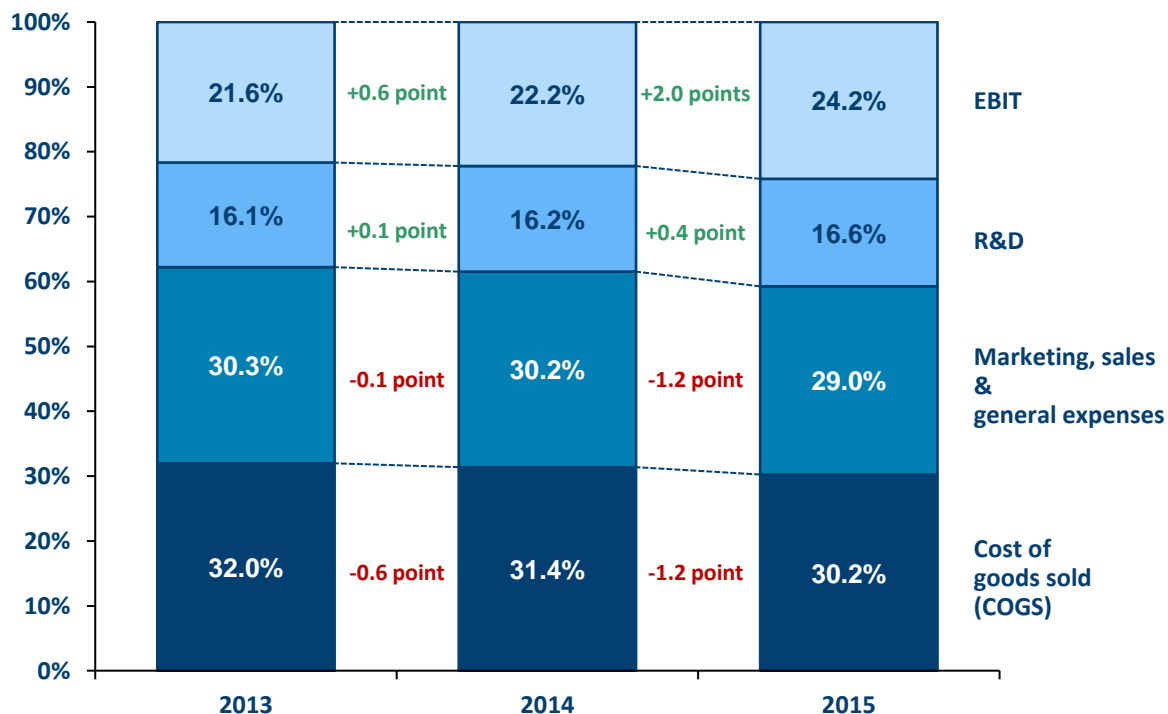
Among the top 30 pharma companies, the trend goes toward an increase of the EBIT and of the R&D expenses while sales and manufacturing costs are slightly decreasing

Global Pharma profitability

Evolution of the top 30 pharma cost structure (2013 – 2015)

Cost structure as a percentage of total revenues¹

Weighted average of total revenues



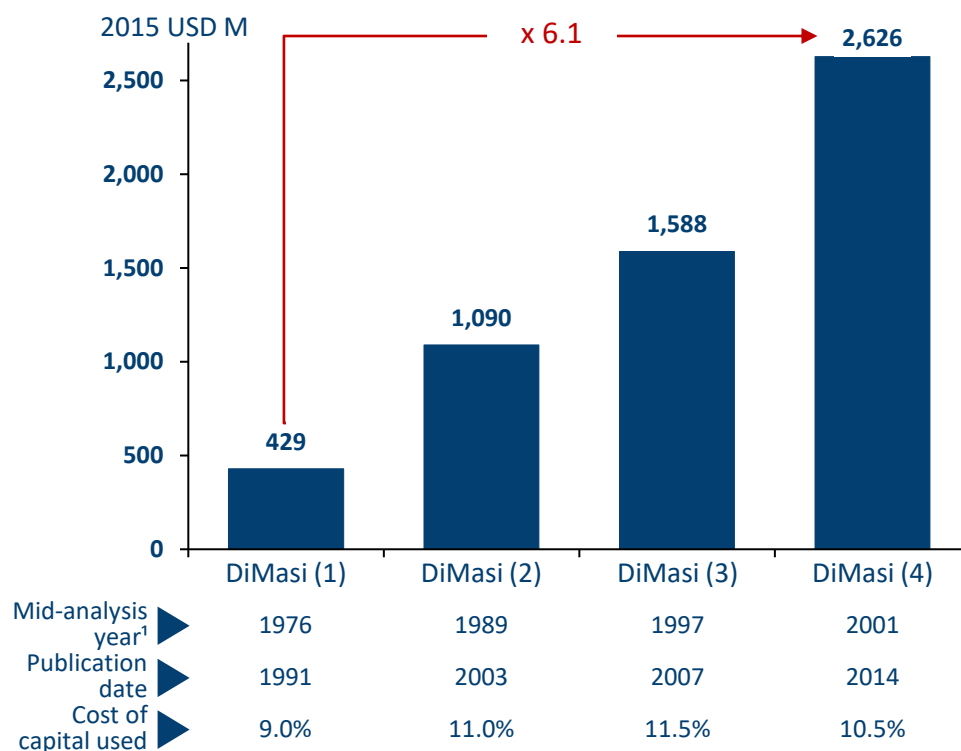
- The analysis of the top 30 pharmaceutical companies in the world shows that their average profitability has increased by 2.6 points between 2013 and 2015
- This improvement can be explained by the restructuring of their product portfolio in which the weight of high-priced secondary care products has been increasing
- Besides, the marketing and sales investment for these specialist-driven secondary care products is much lower than for GP-driven primary care products
- Restructuring and streamlining initiatives have also contributed to improve the economic performance of these companies
- These good performances are the Achilles' heel of pharmaceutical companies when negotiating price and reimbursement of their drugs with governments and payers

The analysis of four studies carried out with the same methodology, shows that the development cost of new drugs has more than sextupled over 25 years

R&D cost estimates

Evolution of R&D costs

Estimated capitalized cost per approved new drug (pre-tax)



- The evolution of the capitalized R&D costs per approved new drug, after neutralization of the inflation, can be mainly explained by:

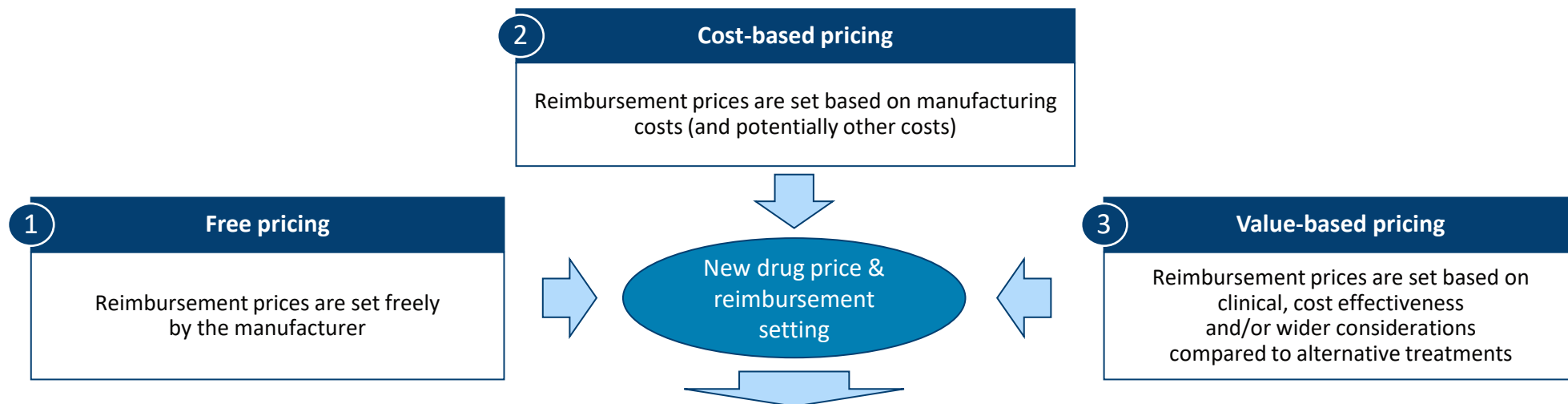
- The growth of the out-of-pocket costs, especially the growth of clinical trials spending: x10.8 between the 1991 and the 2014 estimates (vs. preclinical spending which grew less: x3.9)
- The decrease of the success rates to reach approval from phase I, ranging from 23% in the first 1991 estimates to 12% in the 2014 estimates
- The overall increase of the used cost of capital, even if, in the 2014 estimates a 10.5% cost of capital was used, in decrease of 1 point of percentage from the previous estimates. These assumptions of cost of capital seem overestimated compared to available data from NYU Stern School of Business for biotech products (9.2%, based on 411 firms) and for traditional pharma (7.7%, based on 157 firms)

Note: For the sake of comparability, all values are adjusted to USD 2015 prices using data of the US GDP implicit price deflator from the US. Bureau of Economic Analysis. The GDP implicit deflator shows the rate of price change in the economy, being the ratio of GDP in current local currency to GDP in constant local currency

The price and reimbursement of drugs are set according to three basic principles and implemented through different mechanisms during all their life-cycle

Drug pricing approaches

Drug price setting approaches and life-cycle evolutions¹



Price & reimbursement setting mechanisms during the drugs life-cycle

Internal price referencing	International price referencing ²	Managed entry agreements	Price cuts	Paybacks	Tenders	Compulsory licensing	Voluntary licensing	Tiered pricing
Reimbursement prices are set compared to prices of drugs of the same class	Reimbursement prices are set compared to prices in other countries	Price / volume agreements, risk-sharing agreements, etc.	Post-marketing reimbursement prices reevaluations	<i>A posteriori</i> rebates to healthcare system (PPRS ³ , safeguard clause, etc.)	Competition between similar products	Licensing imposed by a government to a third-party w/o the consent of the patent holder	Out-licensing by a patent holder to a third party to produce and/or market an invention	Differential pricing reflecting the willingness to pay across countries

Sources: "Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research", OECD – "Value-based pricing for pharmaceuticals: Implications of the shift from volume to value", Deloitte – Smart Pharma Consulting analysis

¹ Non-exhaustive list – ² Also called External price referencing – ³ Pharmaceutical Price Regulation Scheme

Value-based pricing aims to set drug prices based on multiple criteria to assess their general impact on the healthcare system or on the society, as a whole

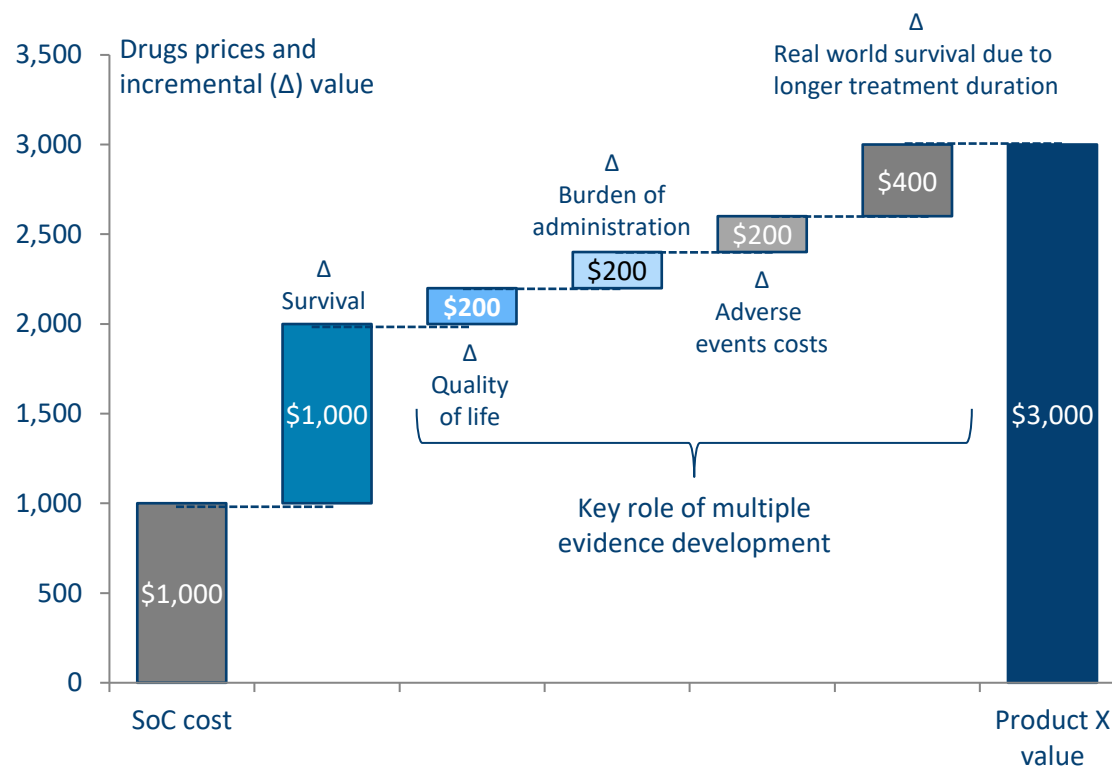
Drug pricing approaches

Value-based pricing – Approach

Definition & analysis

- Value-based pricing (VBP) sets prices based on a value assessment that considers several criteria such as clinical efficacy, cost-effectiveness, or a wider range of criteria including the burden and severity of the disease and the long-term benefits of the treatment
- VBP consists in negotiating prices for new pharmaceuticals based on their value for the society as assessed through Health Technology Assessments (HTA)
- By ensuring access to cost-effective drugs today and incentivizing manufacturers to invest in cost-effective products for the future, VBP seeks to provide a sustainable solution to pharmaceutical price regulation. But while it aims to reward innovation, establishing a clear relationship between the level of innovation and the price is not straightforward

Product X value vs. standard of care (SoC)

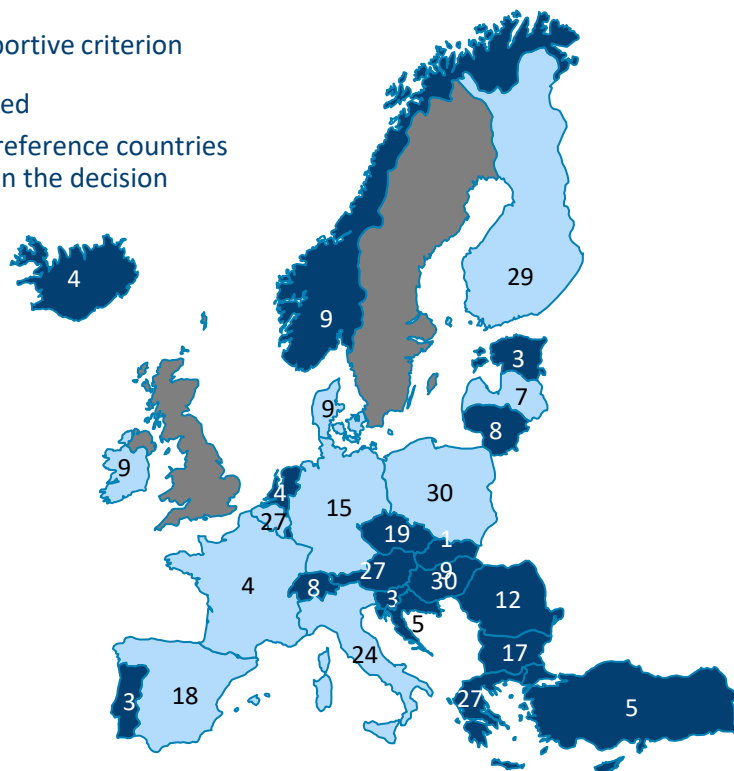


International Price Referencing (IPR) is used in most European countries to set drug prices, but its scope may vary from one country to another

Drug pricing approaches

International price referencing

- IPR is the sole / main criterion
- IPR is a supportive criterion
- IPR is not used
- x Number or reference countries considered in the decision

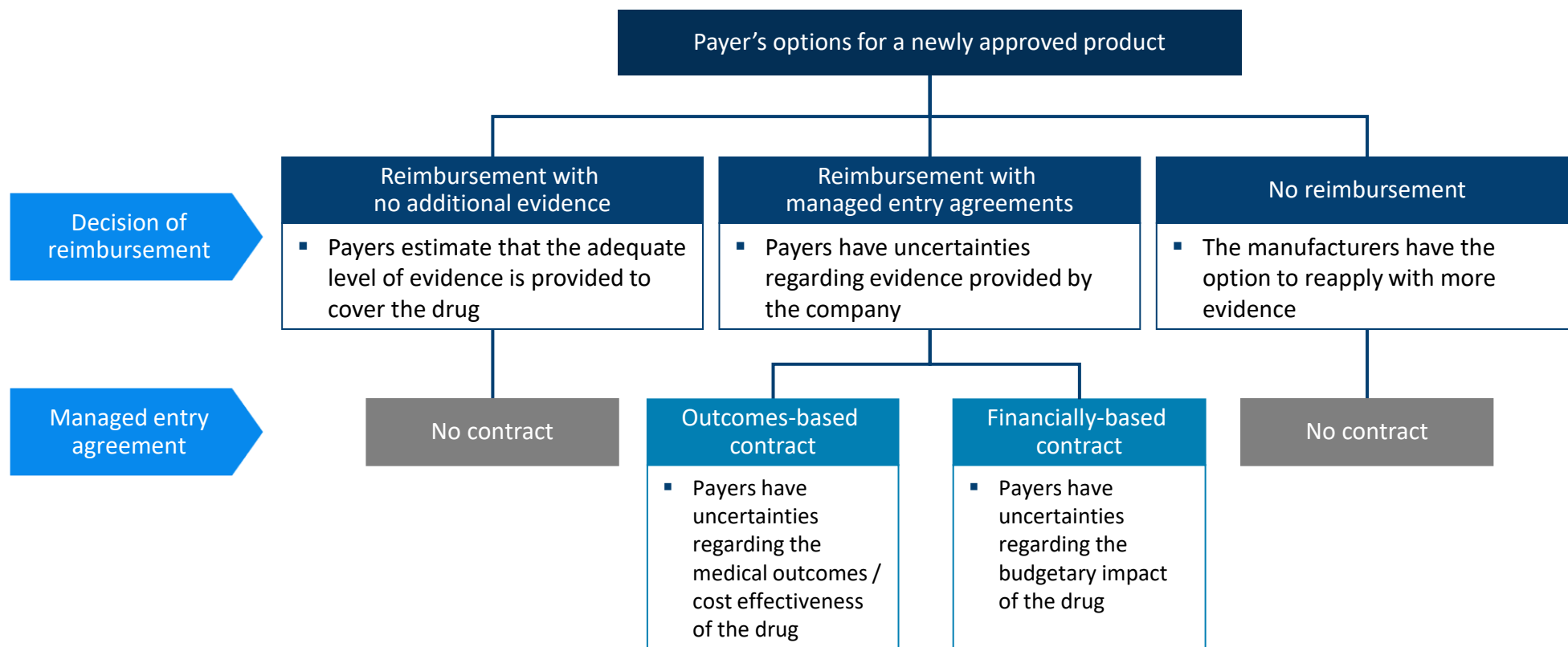


- If most European countries use the International Price Referencing to set the price of drugs, there are some disparities in its usage and calculation:
 - The scope of the use of IPR may depend on the country. For example, in Italy, all reimbursed medicines are concerned while in Spain only new reimbursed medicines with no comparator available are concerned
 - The calculation may also vary. In France, prices should be like those in the reference countries and should not be lower than the lowest price in one of the four reference countries while in Belgium prices are based on the average price in reference countries
 - The revision frequency might also depend on the country with bi-annual revisions in the Netherlands or annual revisions in Spain
 - Ex-factory prices are considered in most European countries, but Norway, Denmark or the Netherlands consider pharmacy purchasing prices

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

Drug pricing approaches

Payer's 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 – Smart Pharma Consulting analysis

Managed entry agreements are expanding to reduce the risk for the payer (efficacy, safety, etc.) and/or to enable pharma companies to negotiate better prices

Drug pricing approaches

Classification of the managed entry agreements

		Outcomes-based contracts	Financially-based contracts
		<ul style="list-style-type: none"> Reimbursement consistent with the public interest, based on the results provided by the pharma company 	<ul style="list-style-type: none"> Limit the economical consequences of the negotiated price
Patient level	1 Biomarker-linked payment	<ul style="list-style-type: none"> Reimbursement based on the results of biomarker tests e.g.: Herceptin (Roche) Erbitux (Merck) Enbrel, Australia (Pfizer) 	<div>4 Per patient cost capitation deals</div> <ul style="list-style-type: none"> Maximum cost set per patient (number of doses, daily cost of treatment, total cost of treatment, etc.) e.g.: Lucentis, UK (Novartis)
	2 Pay-for-performance	<ul style="list-style-type: none"> Reimbursement based on clinical endpoints: <ul style="list-style-type: none"> Morbidity-mortality Clinical efficacy Better adherence e.g.: Velcade, UK (Janssen) Imnovid, FR (Celgene) Aclasta, GE (Novartis) Janumet/Januvia, USA (MSD) 	
Population level	3 Coverage with evidence development (CED)	<ul style="list-style-type: none"> Funding granted if efficacy proven through real life studies Evidence needed to decide whether or not to maintain funding e.g.: Risperdal Consta, FR (Janssen), many high-cost drugs in Italy 	5 Overall sales capitation
			<ul style="list-style-type: none"> Annual sales volume agreement as part of the initial price negotiation Annual value capping with rebates for exceeding sales e.g.: highest cost drugs in France, Enbrel (etanercept) in Australia

Sources: "Innovation et prix du médicament contrats d'accès au marché des médicaments remboursables : choix des schémas d'étude et des critères de jugement", Réseau d'Evaluation en Economie de la Santé, Jan. 2014 – "Unpacking Risk Sharing and Alternative Pricing Schemes"; Pharmaceutical Commerce, Feb. 2010 – "Mechanism Of Coordinated Access (MOCA) and transparent value framework, managed entry agreements", AIFA – Smart Pharma Consulting analysis

Managed entry agreements enable an early access of patients to innovation while also facilitating reimbursement negotiations and limiting the budgetary risk for payers

Drug pricing approaches

Opportunity analysis

Relative importance¹

Payers	<ul style="list-style-type: none"> Potential to re-evaluate the effectiveness of the drugs at a later stage and re-negotiate the price based on real-world evidence and thus to move towards a value-based pricing system 	5
	<ul style="list-style-type: none"> Help address post-licensing uncertainty by offering flexibility in dealing with new and often expensive treatments 	5
	<ul style="list-style-type: none"> Improve the cost-effectiveness through a discount or a payback agreement for non-responders 	4
	<ul style="list-style-type: none"> Potential to create synergies with existing initiatives on registries in Europe: pulling evidence from different countries could allow to generate a large pool of data and increase the statistical significance of the results 	3
	<ul style="list-style-type: none"> Enable different types of schemes addressing different needs, both financial and non-financial 	3
Manufacturers	<ul style="list-style-type: none"> Speed up reimbursement negotiations for drugs which were likely to be rejected by drug reimbursement agencies 	5
	<ul style="list-style-type: none"> 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 	4
	<ul style="list-style-type: none"> Potential to reinforce the long-term collaboration between payers, health authorities and pharmaceutical companies 	4
	<ul style="list-style-type: none"> Enables discounts without impacting list prices 	4
Patients	<ul style="list-style-type: none"> Ability to gain faster access to innovative medicines 	5

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

Drug pricing approaches

Threat analysis

 Relative importance¹

Payers	▪ If managed entry agreements proliferate without integrating with other activities and initiatives, the burden is likely to become too high	5
	▪ 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.	4
	▪ Threat that manufacturers could start proposing higher entry prices in the expectancy of having to engage managed entry agreements	4
	▪ Limited capacity to implement and assess evidence , notably if implementation takes place at regional/hospital level	3
Manufacturers	▪ Costs can partially, and in some cases totally, outweigh benefits	4
	▪ Concessions required such as refunds for non-respondent patients, discounts, gathering of additional data	4
	▪ Voluntary versus no voluntary nature of such contracts leading to a variability in stakeholders' perception across countries	3
Patients	▪ Frequent lack of transparency on the agreements implemented, limiting the ability of patient groups to be aware of such contracts ²	4
	▪ Legal issues regarding individual patient data collection and transfer	4

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

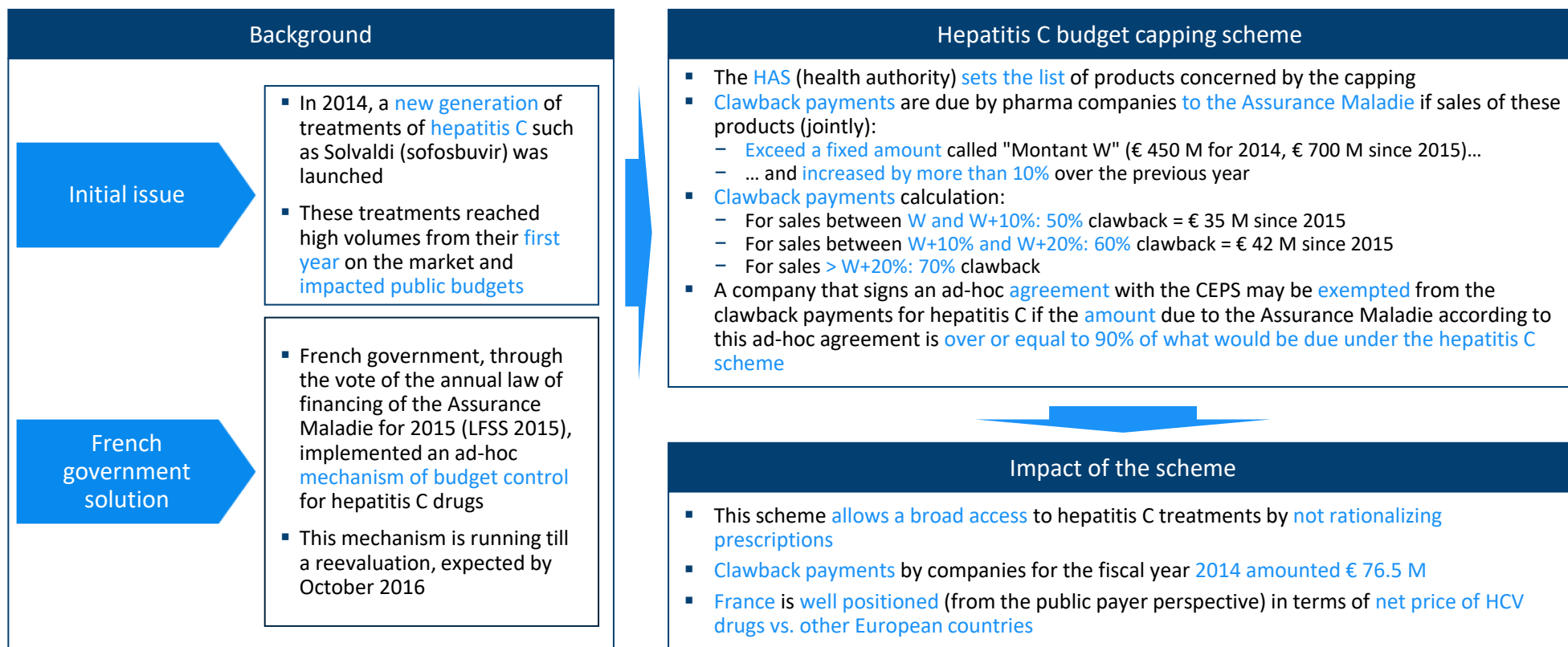
¹ Rating from 5 = very important to 1 = limited importance – ² Except in the UK where the NICE has made available a list of all the approved patient access schemes

Due to their impact on public budgets, French authorities voted a budget capping for all innovative hepatitis C drugs sales

Drug pricing approaches



Case study: HCV budget capping in France



Sources: "Contribution au titre de médicaments destinés au traitement de l'hépatite C", URSSAF – LFSS 2015 et 2016 – "Produits de santé à l'heure des comptes", APICCS – CEPS 2014/2015 annual report – Smart Pharma Consulting analysis

UK 2014 PPRS (Pharmaceutical Price Regulation Scheme) includes one total pharmaceutical sales capping and one profitability capping for the 2014-2018 period

Drug pricing approaches



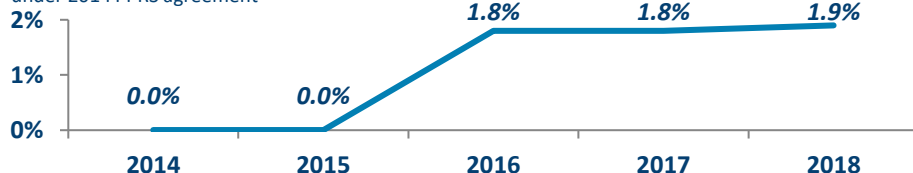
Case study: UK 2014 PPRS

The 2014 PPRS is a voluntary agreement between the British Department of Health (DH) and the Association of British Pharmaceutical Industry (ABPI) which regulates the supply of branded medicines to the NHS¹ by 2018

Sales growth paybacks

- Due to the current state of the global economy and the **financial challenges** facing the NHS, the DH and the ABPI have agreed to introduce a **limit <on the growth** of the **overall cost** of the branded medicines purchased by the NHS
- Payments are made by pharma companies on a quarterly basis of net sales to the NHS of **branded medicines**, i.e. after any other discounts already given
- Smaller companies** with sales to the NHS of less than £ 5 M are exempt from payments and to stimulate innovation, **products with first sales after January 2014** are **not concerned** by this scheme either

Sales growth threshold under 2014 PPRS agreement



Profitability paybacks

- The scheme provides a framework for determining **reasonable limits to the profits** to be made from the supply of branded medicines to the NHS
- There are two **profitability thresholds** that pharma companies choose to refer to (they are designed to be similar):
 - One level of **return on sales** (ROS) target: **6%**
 - One level of **return on capital** (ROC) targets: **21%**
- Within either limits**, companies are **allowed to set and change prices** in line with commercial considerations and NICE² appraisals
- If companies **reach the profit threshold**, they have to **pay 50% of the additional profit** to the NHS and are **not allowed to increase their prices**
- Companies must submit an **Annual Financial Return** to the DH for **control** purpose

An EU collaboration for Health Technologies Assessment exists since 2005 with the aim to set a better communication between HTA bodies and to standardize methodologies

Drug pricing approaches



Initiatives of assessment collaborations in Europe

About EUnetHTA

- EUnetHTA was established in 2005 to create an effective and sustainable network for HTAs (Health Technologies Assessments) across Europe
- EUnetHTA helps develop reliable, timely, transparent and transferable information to contribute to HTAs in European countries
- EUnetHTA supports collaboration between European HTA organizations at the European, national and regional level through:
 - Facilitating efficient use of resources available for HTA
 - Creating a sustainable system of HTA knowledge sharing
 - Promoting good practices in HTA methods and processes



EUnetHTA Joint Action 1 strategic objectives (2010-2012)

- To develop principles, methodological guidance and functional online tools and policies to:
 - Produce, publish, store and retrieve structured HTA information
 - Improve Relative Effectiveness Assessment (REA) by identifying areas where methodological guidance is needed and by providing it, suggesting ways to integrate REA of pharmaceuticals as a special version of the HTA Core Model (methodological framework for production and sharing of HTA information)
 - Structure exchanges and storage of information on evidence generation on new technologies (e.g., registries and trials)
- To test and implement:
 - A web-based toolkit for structured exchanges and storage of information on evidence generation on new technologies
 - The application of the HTA Core model in common production of at least 2 Core HTAs
 - A REA of (a group) of pharmaceuticals in line with the core HTA development
 - Real life support of information flow on new technologies prompting those where parallel assessments of same technologies are detected and alerting on opportunities for information sharing and closer collaboration
 - Provision of a contemporary information management system which supports collaborative HTA work and ensures rapid dissemination of HTA results

EUnetHTA Joint Action 2 strategic objectives (2012-2015)

- To strengthen the practical application of tools and approaches to cross-border HTA collaboration
- To aim at bringing collaboration to a higher level resulting in better understanding for the Commission and Member States (MS) of the ways to establish a sustainable structure for HTA in the EU
- To develop a general strategy, principles and an implementation proposal for a sustainable European HTA collaboration

Voluntary licensing gives patients faster and easier access to medicines, even though this access is not always guaranteed and is restricted by the patent holder

Drug pricing approaches

Voluntary licensing – Approach

Definition

- A voluntary license (VL) is an authorization given by the patent holder of an invention to a third party (e.g., a generic company) to produce, market, import and/or distribute that invention in return for a payment of royalties¹
- VLs are also referred to as “out-licensing” and do not necessarily include technology transfer. Thus, the Indian affiliate of Merck & Co has recently signed a marketing deal with Sun Pharmaceuticals for two patented diabetes drugs (Januvia and Janumet) that will be marketed under different brand names in India
- Depending on the terms of the agreement, the licensee:
 - May act as an agent of the patent holder, with limited freedom, and receive fee
 - or
 - Be free to set the terms of sale and distribution within the agreed geographical area, contingent on payment of a royalty
- VLs were requested by the civil society and health groups for more than 15 years to bring more competition on drug price

Analysis

- VL is a strategic decision, which is a means to:
 - Prevent compulsory licensing imposed by governments²
 - Limit the risks of patent challenges and of “copies” produced by generic companies (by signing agreements with them)
 - Enable the patent holder to reach lower income markets
 - Protect the corporate reputation (by contributing to facilitate the access to medicines, especially in low and lower-middle income countries)
- The terms of the VL agreement are set by the patent holders who will stipulate certain conditions such as:
 - The scope: countries and market segments (e.g., public vs. private, hospital vs. open care, etc.)
 - Possibilities to produce, market, import and/or distribute
 - The quality requirements
 - The exclusivity, semi-exclusivity or non-exclusivity of the license
 - Price ranges
 - Duration (e.g., three years, five years)
 - The amount of royalties to be paid

Note: The 1st VLs have been given by GSK and Boehringer Ingelheim following the South African competition case of 2002 regarding antiretrovirals (ARVs)

Sources: Tahir Amin (2007), IFPMA (2013), P. Londeix MDM (2014) – Smart Pharma Consulting analysis

¹ In certain circumstances, a license can be granted to an intermediary sub-licensing agency, such as the Medicine Patent Pool founded by UNITAID since 2010, which will be allowed to negotiate licensing terms with interested licensees –

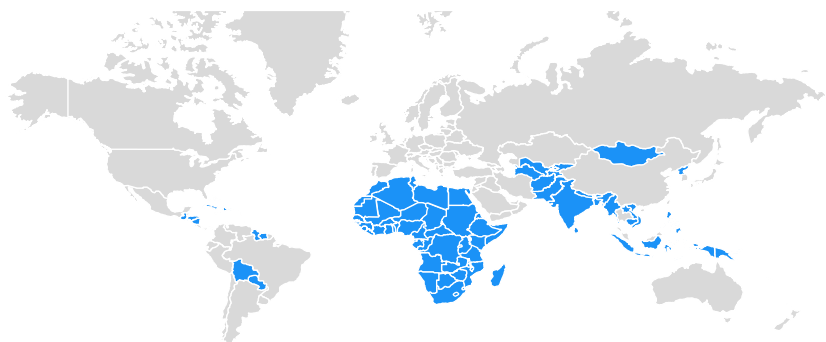
² Such as India, Malaysia, Brazil, Mozambique, Zambia, Zimbabwe, Ghana, Eritrea, Thailand, Ecuador, Indonesia

Gilead agreed on a voluntary licensing agreement with 14 different generic companies for the marketing of its HCV drugs in 101 low-income countries

Drug pricing approaches

Voluntary licensing – Gilead case

Gilead's voluntary licensing agreements



- Gilead has signed licensing agreements for sofosbuvir (Sovaldi), ledipasvir/sofosbuvir (Harvoni) and velpatasvir/sofosbuvir with 11 international generic companies for the distribution in 101 developing countries:
 - Aurobindo Pharma, Biocon, Cadila Healthcare, Cipla, Hetero, Laurus, Mylan, Natco, Ranbaxy, Sequent Scientific, Strides Arcolab
- Gilead has also signed agreements with three local generic companies for in-country production and distribution:
 - Ferozsons laboratories (Pakistan)
 - Magic Pharma (Egypt), Pharmed Healthcare (Egypt)

- Licensees will receive a complete technology transfer of the Gilead manufacturing process...
- ... and will be free to set the price level of sofosbuvir and of ledipasvir/sofosbuvir
- The countries included in these agreements account for 103 million people living with hepatitis C (i.e., 67% of the total global infected population)...
- ... but it does not guarantee an actual access to treatment due to the lack of basic health facilities or to the high HCV burden
- Price will not drop if competition in each country is low
- Gilead will receive royalties' payment of 7% of the generic price for sofosbuvir and the single tablet regimen of ledipasvir/sofosbuvir to support:
 - Product registrations
 - Medical education and training
 - Safety monitoring

Note: In these 101 countries, Gilead offers its HCV medicines at a suggested government price of USD 300/month of treatment for Sovaldi and USD 400/month for Harvoni

GSK which was one of the first vaccine companies to adopt a tiered pricing approach for its vaccines, has designed a new model in 2013 with seven different tiers

Drug pricing approaches

Pricing differentiation or tiered pricing – GSK case

Ability to Pay

- For public markets, GSK's pricing policy focusses on expanding access via national immunization programs at affordable prices for governments
- Maximum prices and country membership in a pricing tier are defined by Gross National Income (GNI) per capita which is used as an indicator of governments ability to pay
- GSK's approach to public sector prices is organized into seven tiers according to the GNI ranking of the countries
- The tier 7, the lowest, corresponds to GAVI¹ eligible countries
- The remaining three World Bank groups of HIC (High Income Countries), UMIC (Upper Middle-income Countries) and LMIC (Lower Middle-income Countries) will each comprise two tiers
- Increasing the number of tiers enables GSK to be more finely attuned to a country's ability to pay
- Introducing a more formalized and transparent approach should also support governments - particularly those in the process of transitioning out of Gavi support - with their budget planning

Willingness to Invest

- Each Income Tier is divided into price ranges based on four criteria, three of which incentivize public health policy commitments to vaccination:
 1. The committed duration for vaccination in the disease area
 2. The coverage of the target population which rewards the health benefit of well implemented vaccination program
 3. For vaccines with broad age recommendations such as cervical cancer vaccines, a government's commitment to vaccinate catch-up cohorts as part of their national immunization program
- The fourth criteria is the committed number of doses to be purchased; it is weighted less than previous ones together to ensure that governments with small populations who are fully committed are not disadvantaged by their size
- In 2016, 16 countries are in the process of transitioning out of Gavi support. These countries have successfully implemented mass vaccination program with new vaccines but are still struggling with the cumulative effect of these programs on national immunization budgets. GSK will provide them with pricing support to transition to their respective Tiers as they are transitioning out of Gavi support

Sources: GSK's Tiered Pricing Approach for Vaccines", 2014 – Gavi website – Smart Pharma Consulting analysis

¹ GAVI is a nonprofit organization based in Geneva that facilitates the purchase of vaccines. It creates a more attractive vaccines market by bringing together 72 developing countries under one umbrella and raising funds from leading donors – largely industrialized-country governments and key multilateral organizations – for the purchase of vaccines. The procurement process is handled through UNICEF

Partnering with patient advocacy groups may help pharma companies generate awareness, shape favorable regulations and obtain earlier access and payer coverage

Drug pricing approaches

Influence of Patient Advocacy Groups on pricing and reimbursement decisions

Opportunity to partner with patient advocacy groups (PAGs) (examples)

Generating awareness	Shaping the regulation / legislation	Claiming payers' coverage
<ul style="list-style-type: none"> ▪ The question of the funding of expansive hospital drugs was questioned in the Netherlands since the mid-90 ▪ The public consultation included regulators, hospitals and private reimbursement companies but excluded patients and specialists ▪ It was agreed to cover expansive hospital drugs partly between hospital budgets and private insurances, based on a negotiable percentage ▪ Patient organizations in the field of breast cancer (BNV, NFK) raised the political awareness that patients would face inequalities in the access to Herceptin (Roche) since hospitals have different budgets and healthcare resources allocations 	<ul style="list-style-type: none"> ▪ Patient advocacy groups can be instrumental in the development of drugs regulation or legislations ▪ That was the case in the formation of orphan drug legislations in the USA (US Orphan Drug Act) and in the EU (CE n°141/2000). Patients' organizations such as NORD (USA) or EURODIS (EU) played the role of "surrogate pressure groups" and played a key role during the drafting of legislations ▪ Another example was found in the USA when the Centers for Medicare & Medicaid Services (CMS) proposed to reduce the number of "protected classes" covered by Medicare part D plans¹, i.e., to remove antidepressant, immunosuppressant and antipsychotic classes. Several patient advocacy groups partnered within the Partnership for Part D Access to lobby against CMS proposal 	<ul style="list-style-type: none"> ▪ Patient advocacy groups often play an important role to promote the drug coverage by payers ▪ This statement is particularly true for the coverage of orphan drugs for rare diseases ▪ For example, patient advocacy groups played an important role for the promotion of R&D and in arguing for the full reimbursement of Cerezyme (Genzyme) in the treatment of Gaucher's disease. Genzyme also partnered with the humanitarian organization project HOPE with the aim of guaranteeing the reimbursement of Cerezyme around the world

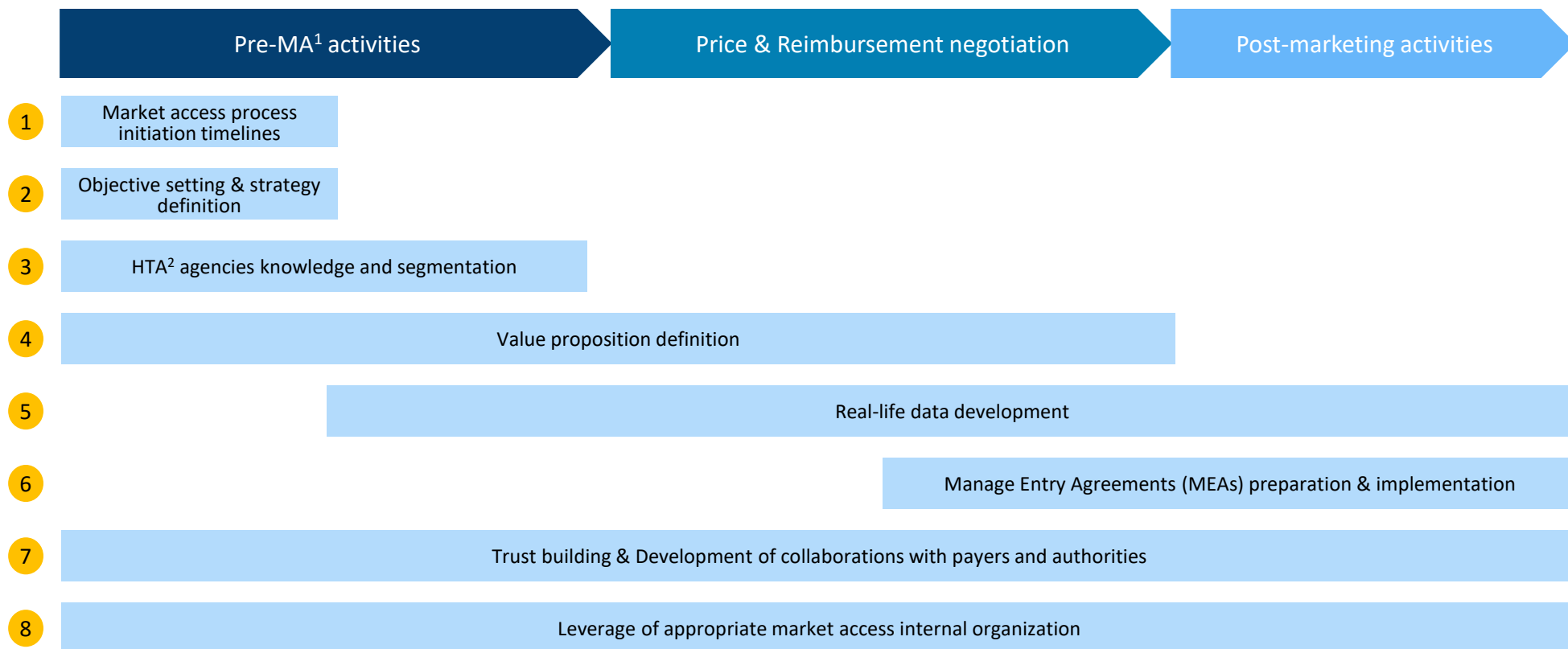
Sources: "Orphan drug legislation: lessons for neglected tropical diseases", International journal of health planning and management – "Access to Orphan Drugs: A Comprehensive Review of Legislations, Regulations and Policies in 35 Countries", PLOS ONE – Partnership for Part D Access website – "The impact of patient advocacy: the case of innovative breast cancer drug reimbursement", Sociology of Health & Illness Vol

¹ Classes in which all drugs are covered by Medicare under Part D plans (anti-retrovirals; immunosuppressant when used for organ rejection; anti-depressants; anti-psychotics; anti-convulsant agents; and anti-neoplastics)

The best practices related to the market access process are well identified from the pre- to the post-marketing authorization phases of products

Best practices

Market access best practices

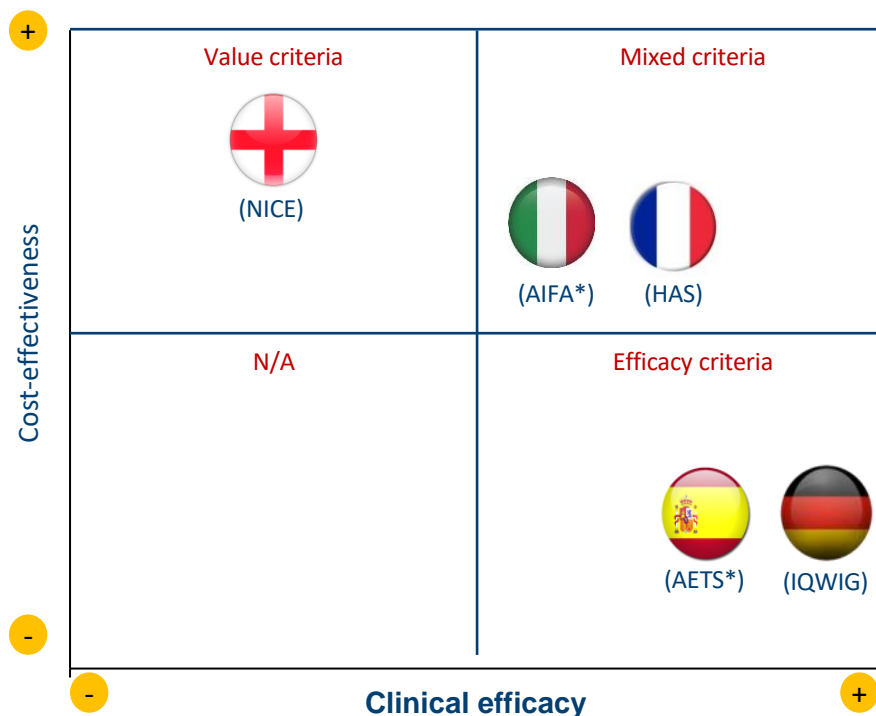


Pharma companies may cluster HTA agencies according to the assessment criteria they value the most and then develop a specific value proposition for each of them

Best practices

Payers' knowledge and segmentation

Segmentation of EU countries based on HTA criteria

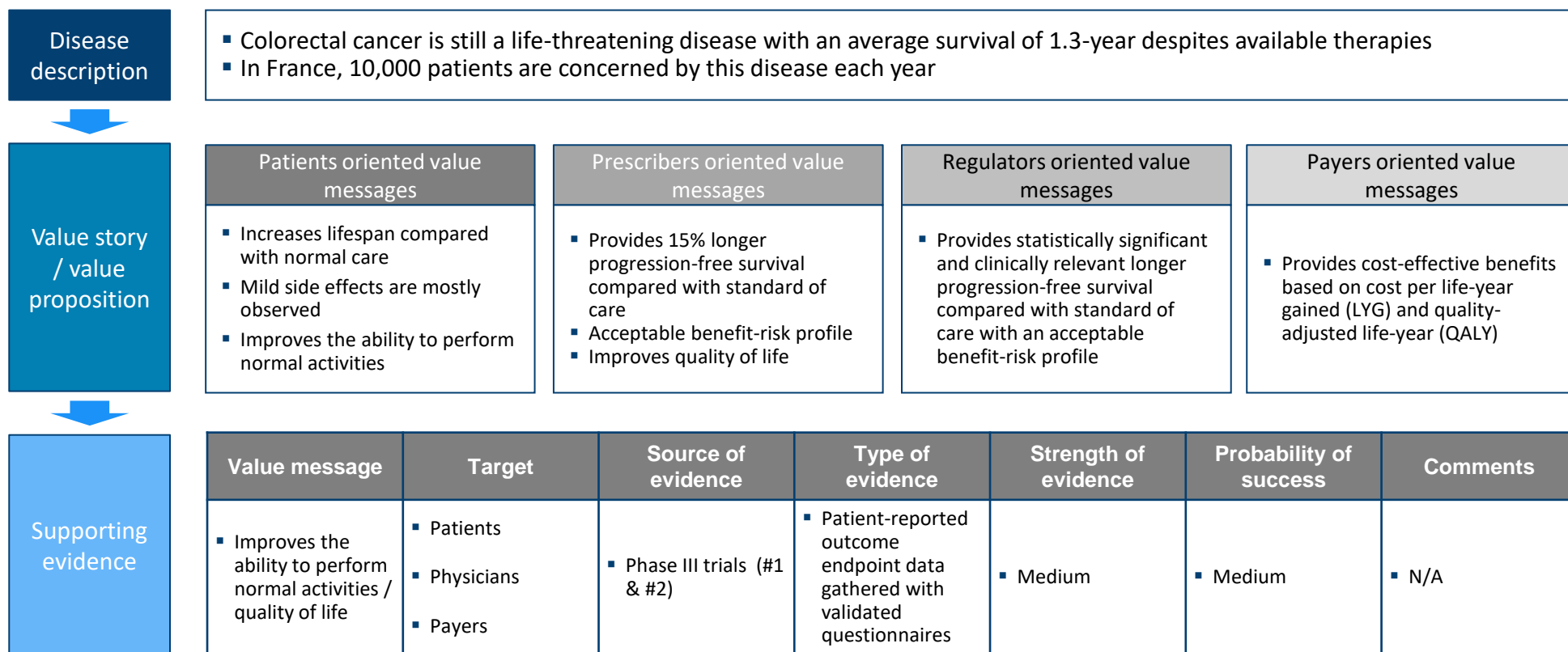


- The first step for market access activities planning is to understand **what will drive national HTA** (Health Technology Assessment) agencies **decisions** when it comes to drug evaluation
- A good understanding of their requirements will allow to define an **appropriate value proposition** for each of them
- The "one fits all" strategy is no longer valid since each country has different requirements
- HTA agencies can be segmented according to the importance they grant to the following criteria:
 - Clinical efficacy vs. cost-effectiveness
 - Absolute¹ vs relative therapeutic value²
 - Narrow view vs. holistic view of the impact of the drug (Health Related Quality-of-Life, societal impact, etc.)
 - Importance of subpopulations

Value dossiers may help to develop targeted key messages for the different stakeholders

Best practices

Value proposition definition – The value dossier: Example



Pharma companies can enhance the perception of their value proposition by providing beyond or around-the-pill services which are likely to be valued by payers

Best practices

Value proposition definition – Development of payer-oriented services

Patient support programs	Tools to improve the management of healthcare resources	Connected devices to follow up patients' adherence and generate real-life data
<ul style="list-style-type: none"> ▪ In the current environment where payers require more complex and meaningful data to cover innovations, the development of real-world evidence is often a must-have ▪ Thus, observational studies and comparative effectiveness research should be developed to gather clinical, economic and patient-reported outcomes ▪ In that context, patient support programs may take an important meaning by binding them to outcomes and real-life result generation 	<ul style="list-style-type: none"> ▪ In 2013, GSK, in collaboration with CCNC¹ (a private payer from North Carolina, USA), launched a tool to analyze patient medication challenges ▪ This analytical tool is based on patient information such as prescription history, hospital admissions or discharge data ▪ The service then provides prescribers with suggestions of interventions which are expected to facilitate a better patient engagement when facing medication challenges ▪ The project was based on the fact that USD 290 B spending due to poor medication adherence in the USA could be potentially avoided 	<ul style="list-style-type: none"> ▪ In 2014, Merck KGaA launched a project to generate real-life data and improve multiple sclerosis management with two components: <ul style="list-style-type: none"> – A connected device for its multiple sclerosis treatment Rebif (interferon beta-1a). The device collects injection data and sends it wirelessly to a server – A web-based software for patients to engage in the management of their disease by completing short forms (Quality of Life) ▪ The project allows: <ul style="list-style-type: none"> – Patients to receive email or SMS reminders – Physicians and nurses to monitor patients adherence – Merck to generate real-life adherence and quality of life data

Patient advocacy groups and pharma industry may improve the quality of their relations and partnerships by following simple recommendations

Best practices

Collaborations with patients' advocacy groups (PAGs)

Recommendations to improve industry / patient advocacy group partnerships

Recommendations for pharma companies

- 1 Improve transparency and authenticity
- 2 Seek PAGs input in the design and execution of clinical trials
- 3 Involve PAGs in awareness and education campaigns for patients, healthcare providers and caregivers
- Provide follow-up when meetings are convened to seek
- 4 PAGs counsel on unmet needs
- Use request for proposal / grant-giving process to
- 5 reward collaboration among patient groups rather than competition

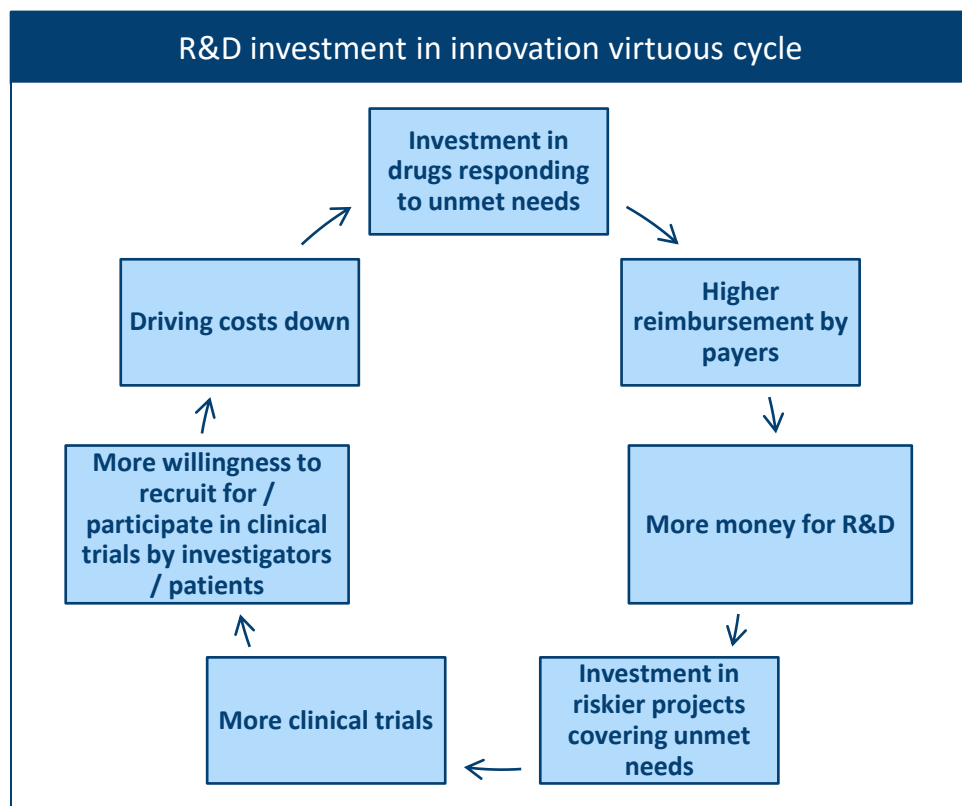
Recommendations for patients' advocacy groups

- 1 Be clear about the scope of partnerships they will agree to bind
- 2 Behave more like businesses, meeting commitments in a timely fashion
- 3 Stay focused on their core missions and avoid initiating programs simply to chase more funding
- 4 Frequently report back to funders on the impact of money raised and spent
- 5 Establish more patient registries that pharma can use for drug trials recruitment

Pharma companies' corporate reputation is directly related to their research announcements responding to previously unmet needs

Corporate reputation leverage

Corporate reputation building – Involvement in R&D



Patient-centric mindset for an improved corporate reputation

- A reputation benchmark performed by Alva showed that pharma companies **reputation peaked** when were announced **patient-driven breakthrough research initiatives**:
 - **AstraZeneca's** reputation was improved when was announced in 2014 a partnership with Eli Lilly for the development of **Alzheimer** treatments based on **genome-editing technology**. It also peaked when was announced its partnership with **PatientsLikeMe** in 2015
 - **Merck's** reputation peaked in 2015 with the announcement of its partnership with Genea Biomedx and with Illumina for the development of **pioneering assisted reproductive treatments**
 - **GSK's** reputation also peaked with the announcement of R&D innovations such as **Ebola vaccine** reaching phase II during late 2014 or **malaria vaccine** being approved by the EMA and soon to be used in Africa

Sources: "Pharma industry improves its tarnished reputation", CenterWatch News Online – "R&D innovation – a reputation differentiator for pharma", Alva – Smart Pharma Consulting analysis – Merck press release

The Pharma Corporate Reputation Audit developed by Smart Pharma Consulting facilitates the identification of key challenges to improve corporate reputation

Corporate reputation leverage

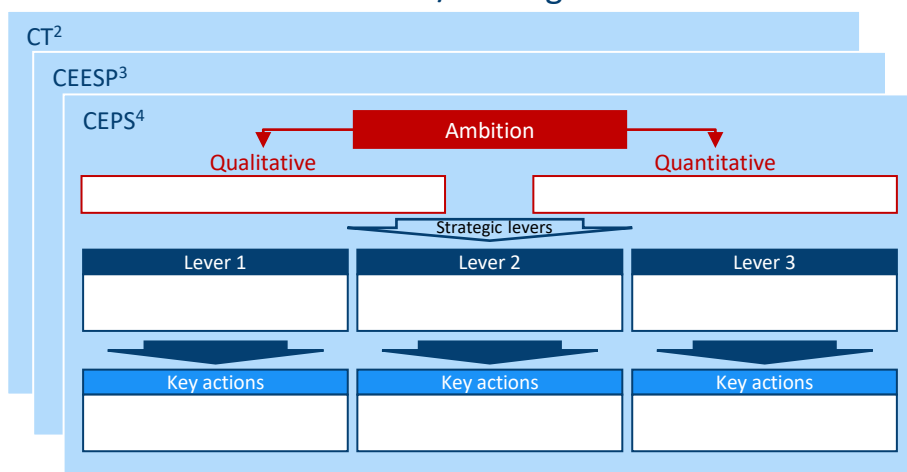


Corporate reputation strategy & tactics

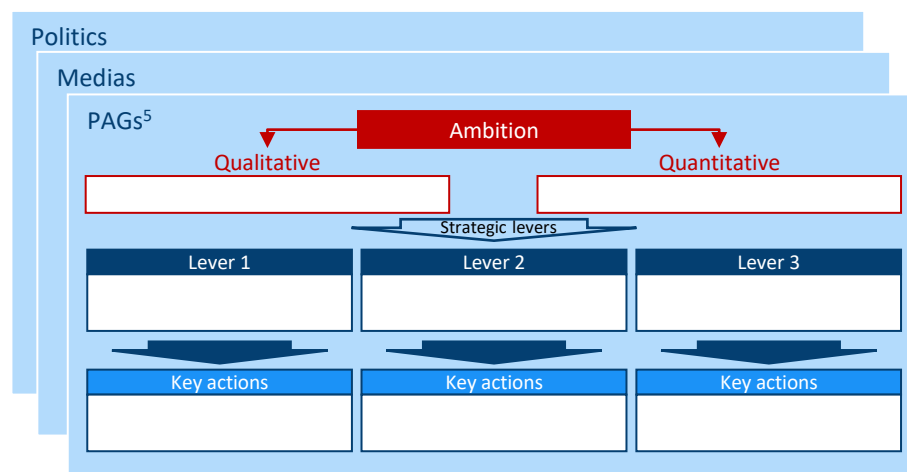
Illustrative - France

Pharma Reputation Strategy Card

HTA¹ / Pricing



Access environment



- Strategy and related actions aim at achieving the set ambition in terms of corporate reputation improvement
- The Pharma Reputation Strategy Card can be applied for one stakeholder group (i.e., HTA / Pricing, Access environment...) or sub-group (i.e., CT, CEESP, CEPS, Etc.), or even for one individual stakeholder (i.e., President of the CEPS)
- Strategic levers correspond to strengths on which the company should capitalize to create a competitive advantage or weaknesses to be corrected

Market access strategy and corporate reputation play a key role to optimize drug price valuation and to take the advantage over competition

Recommendations

Selected key takeaways

- Pressure of governments and payers on drug prices will keep on increasing but the impact within the same category of drugs will significantly differ, depending on market access strategy design and execution by pharma companies

DON'Ts

- Justify the price of innovation by the level of investment in R&D which is almost half the one invested in marketing, sales and general expenses
- Invoke the high level of risk, knowing that there is no case of bankruptcy amongst pharma companies
- Invest in sophisticated and expansive health economic studies which will be most likely criticized and not taken into consideration to grant you a better price
- Propose managed entry agreements for which the uncertainty associated with outcomes is high
- Underestimate the importance of corporate reputation

DOs

- Pharma companies should act in good faith and put themselves in governments and payers' shoes
- Put forward evidence that are well-documented and articulated in a convincing argument to support the asking price
- Managed entry agreements should remain as simple as possible and generate a minimum of controlled associated costs
- Each pharma company should strengthen its corporate reputation to differentiate itself positively from competitors and thus get preferred

... knowing that pharma companies are not considered as all equal by governments and payers in the context of drug pricing & reimbursement

Consulting firm dedicated to the pharmaceutical sector operating
in the complementary domains of strategy, management and organization

The Collection 2021

- The “Collection 2021” which includes Smart Pharma Consulting best position papers, is published on its 20th anniversary
- This e-book proposes effective and practical solutions to help pharma companies improve their performance
- Its content will be released in six parts, over the 4th quarter 2021:

1. Market Insights	4. Sales Force Effectiveness
2. Strategy & Market Access	5. Management
3. Medical Affairs & Marketing	6. Training Programs

Part 2

Strategy & Market Access

- This 2nd part of Smart Pharma Consulting’s best position papers, covers the following topics:
 - Top 20 Pharma Companies
 - Pharma Strategy Crafting
 - Pharma Strategy at Affiliate Level
 - Best-in-class Pharma BD&L
 - Patient-centric Strategy
 - How to boost Corporate Reputation
 - How can Creativity boost Performance
 - Drug Value & Access Optimization

Smart Pharma Consulting Editions



- Besides our consulting activities which take 85% of our time, we are strongly engaged in sharing our knowledge and thoughts through:
 - Our teaching and training activities
 - The publication of articles, booklets, books and expert reports
- More than 80 publications, in free access, can be downloaded from our website, of which:
 - 19 business reports (e.g., The French Pharma Market)
 - 12 position papers in the “Best-in-Class Series”
 - 18 position papers in the “Market Insights Series”
 - 10 position papers in the “Smart Tool Series”
 - 10 position papers in the “Smart Manager Series”
- Our research activities in pharma business management and our consulting activities have shown to be highly synergistic
- We hope that this new publication will be useful for you
- We remain at your disposal to carry out consulting projects or training seminars to help you improve your operations

Best regards

Jean-Michel Peny