

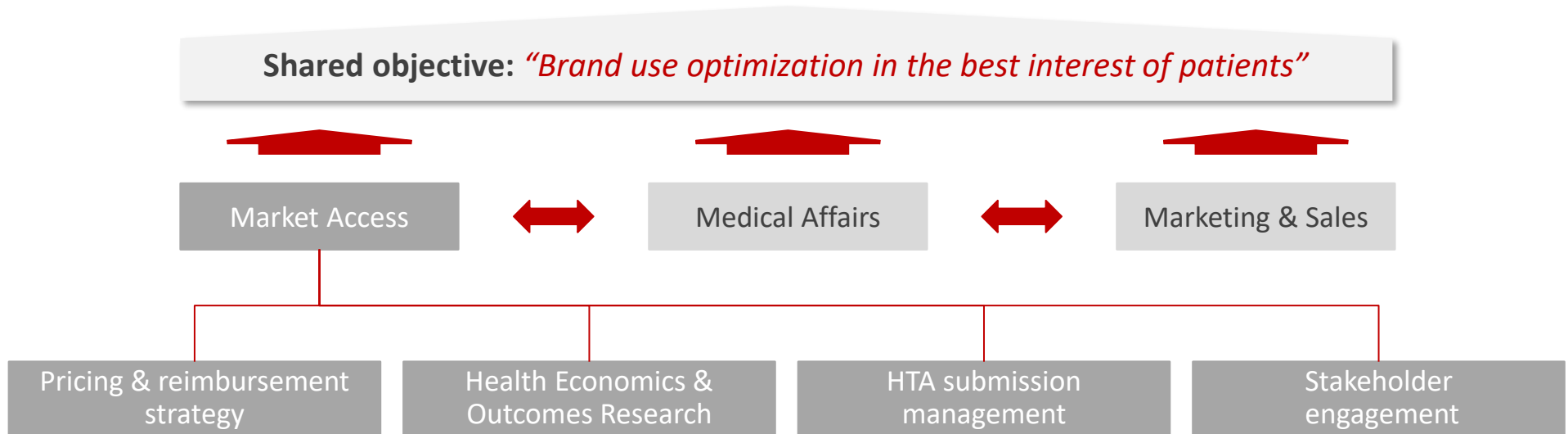


National Market Access Brand Plans

Recommendations for Affiliates

Market Access is, along with the Medical Affairs and Marketing & Sales departments, essential to ensure patients can access drugs while securing an acceptable price for pharma companies

Introduction



- The Market Access department core mission is to ensure that patients can access the Brand, with an acceptable price and reimbursement level
- Thus, the Market Access department participates to the commercial success of drugs and determines to which extent they will reach patients

- From a drug perspective, it is essential that the Market Access, Medical Affairs and Marketing & Sales departments¹:
 - Share the same objective
 - Craft a common strategy to meet this objective
 - Coordinate their activities
 in their field of expertise, while complying with regulations

Sources: Smart Pharma Consulting

¹ As well as Clinical Development, Regulatory Affairs, Government and Political Affairs departments

The purpose of the affiliate market access brand plan is to properly allocate the right resources to secure marketing authorization, pricing and reimbursement and optimize the brand value

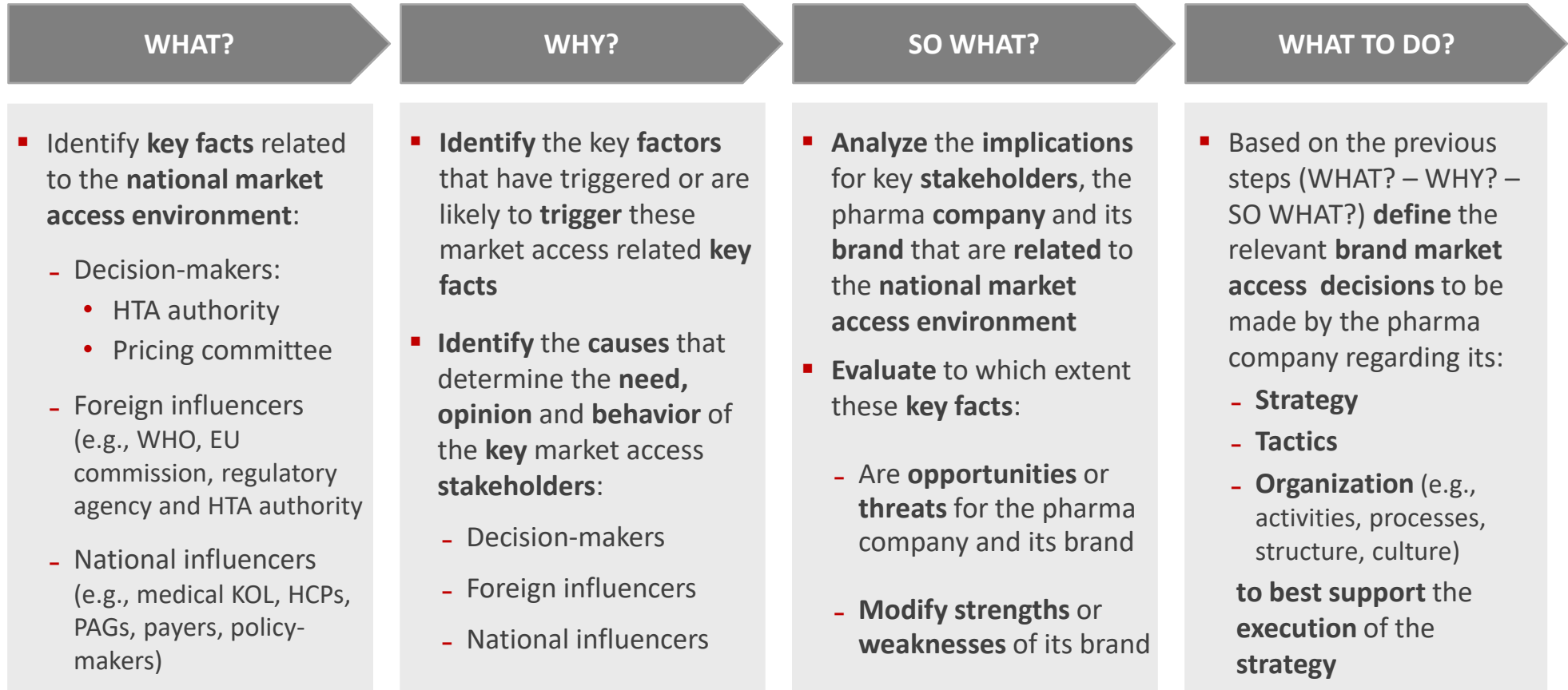
Why crafting a market access brand plan?

- To **prioritize** the market access **activities** to be carried out, **based on**:
 - The analysis of the national **market access environment** (e.g., epidemiology, disease burden¹, medical care, patient care management)
 - The **need, opinion** and **behavior** of:
 - Decision-makers (e.g., Regulatory agency, Health Technology Assessment (HTA) authority, pricing committee)
 - Foreign influencers (e.g., WHO, EU commission, EU regulatory agency, EU HTA authority, US “Most Favored Nation” drug pricing policy)
 - National influencers (e.g., medical KOLs, HCPs, PAGs, patients, payers, policy-makers)
 - The **market access objective** for the brand (e.g., price negotiation, time to market, expansion of reimbursed indications and/or eligible patient population)
 - The **market access strategy** crafted to achieve this objective
- To **organize** the **execution** of these **market access activities** in **synergy with other departments** (e.g., clinical development, regulatory affairs, political and government affairs, medical affairs, marketing and sales) of the pharma company
- To **monitor** the quality of **execution** and the **impact** of these **activities**

PURPOSE 

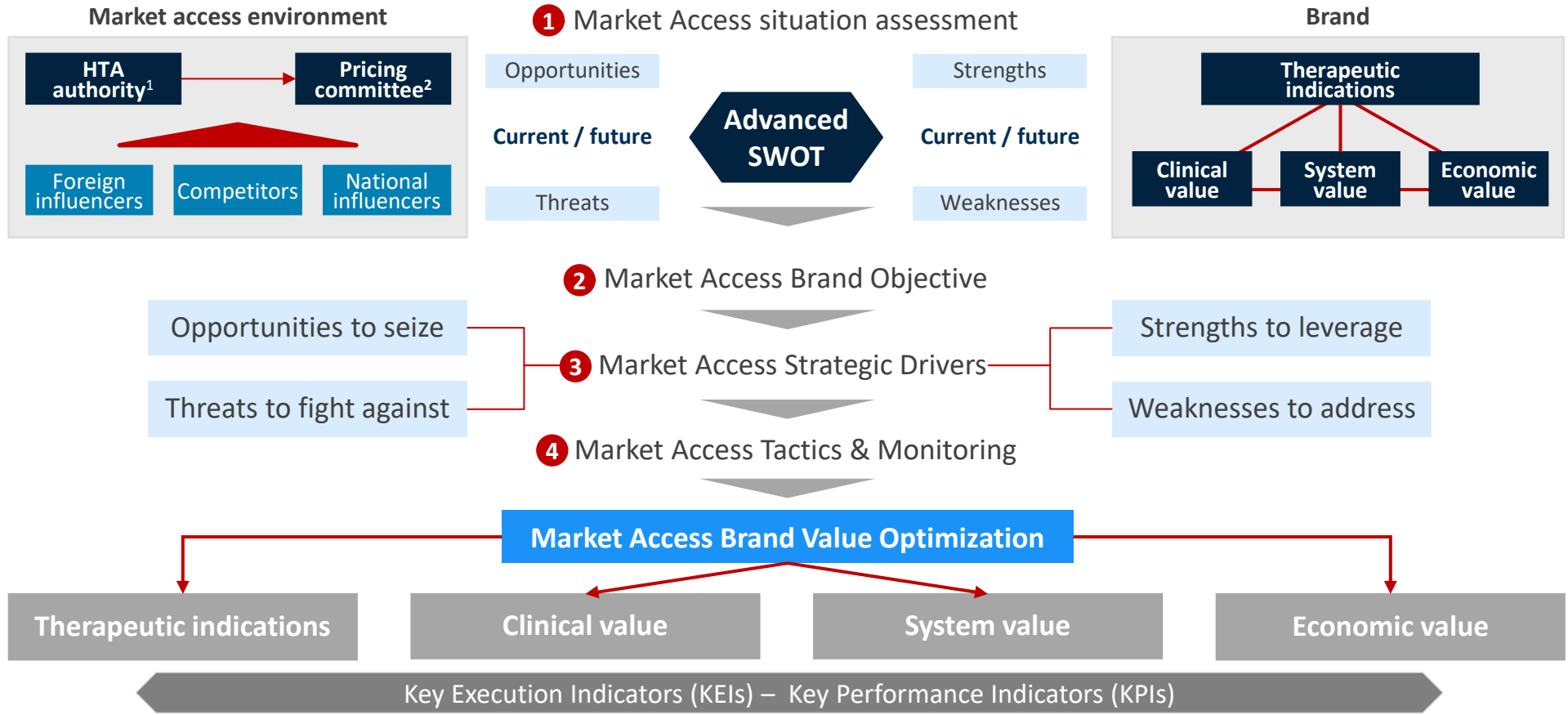
We suggest to adopt the 4 Ws¹ framework to reinforce the relevance and consistency between the national market access situation, objective, strategic imperatives and corresponding tactics

How to draft a market access brand plan?



This four-step thinking process enables to craft the medical strategic drivers to achieve the key medical objective set through the activation of the brand optimization levers

Market access brand planning process



Sources: Smart Pharma Consulting

¹ Health Technology Assessment Agency named HAS (National Authority for Health) in France –
² Named CEPS (Economic Committee on Healthcare Products) in France

The situation assessment should focus on identifying and analyzing current and future key market access environment features from which implications for the brand will be drawn

1 Market Access situation assessment



1. Carry out an **in-depth** and **rigorous analysis** of the **market access environment** related to the claimed indications:
 - Epidemiology (prevalence, incidence, survival rate)
 - Clinical burden (disease progression, symptoms, disability, functional impairment, QoL, unmet medical needs)
 - Economic burden (medical and non-medical costs, SoC)
 - Social & Societal burden (dependence, impact on caregivers and families, operational strain on the healthcare system)
2. Gather **reliable quantitative** and **qualitative essential data** (the WHAT)
3. Understand the **causes that drive these data** (the WHY)
4. Draw the **market access implications** (the so WHAT) for the **brand** from the WHAT and the WHY
 - Patient care management
 - Stakeholders (incl. influencers and competitors)



- **In-depth** market access environment knowledge and understanding (**insights**) **enable** to **identify** and **evaluate**:
 - Major **market access** environment **opportunities** and **threats** for the brand
 - **Brand market access strengths** and **weaknesses** vs. Standard of Care (SoC) and other therapeutic alternatives

The following chart is an enabling tool to identify and analyze the key facts and figures relative to epidemiology, disease burden and patient care management

1 Market Access situation assessment – Introduction

Illustrative

Specificities related to the brand indications	Key Facts & Figures – WHAT?	Driving Factors – WHY?	Implications – So WHAT?
Epidemiology			
Clinical burden			
Economic burden (incl. SoC)			
Social & Societal burden			
Patient care management			

The identification and analysis of the impact of key foreign influencers on national market access decisions is an important part of the situation analysis

1 Market Access situation assessment – Foreign influencers

Illustrative

Key stakeholders	Key Facts & Figures – WHAT?	Driving Factors – WHY?	Implications – So WHAT?
WHO (e.g., essential medicines list, standard of care, disease burden frameworks)			
EU commission (e.g., data exclusivity, incentives, orphan drugs rules)			
EU regulatory agency (e.g., European Medicines Agency)			
EU HTA authority (since 2025 for oncology drugs, ATMPS ¹)			
Pricing committees decisions across EU countries ²			
US MFN ³ drug pricing policy			

Sources: Smart Pharma Consulting

¹ Advanced Therapy Medicinal Products – ² In case ERP (External Reference Pricing) method is applied by national drug pricing committees – ³ Most favored Nation

The opinion and behavior of national stakeholders who have an influence on market access decision-makers should also be carefully analyzed

1 Market Access situation assessment – National influencers

Illustrative

Key stakeholders		Key Facts & Figures – WHAT?	Driving Factors – WHY?	Implications – So WHAT?
Medical KOLs				
HCPs				
PAGs – Patients				
Payers	Public health insurers			
	Private health insurers			

Policy-makers	Government			
	Politicians			

Once the MA¹ has been granted by the regulatory agency², the key challenges are to optimize the brand evaluation by the HTA authority and the negotiation with the pricing committee

1 Market Access situation assessment – National decision-makers

Illustrative

Key stakeholders		Key Facts & Figures – WHAT?	Driving Factors – WHY?	Implications – So WHAT?
Regulatory agency (e.g., ANSM in France)				
HTA authority (e.g., HAS in France)	CEESP (commission in charge of economic assessment in Public Health)			
	CT (transparency committee)			
Pricing committee (e.g., CEPS in France)				

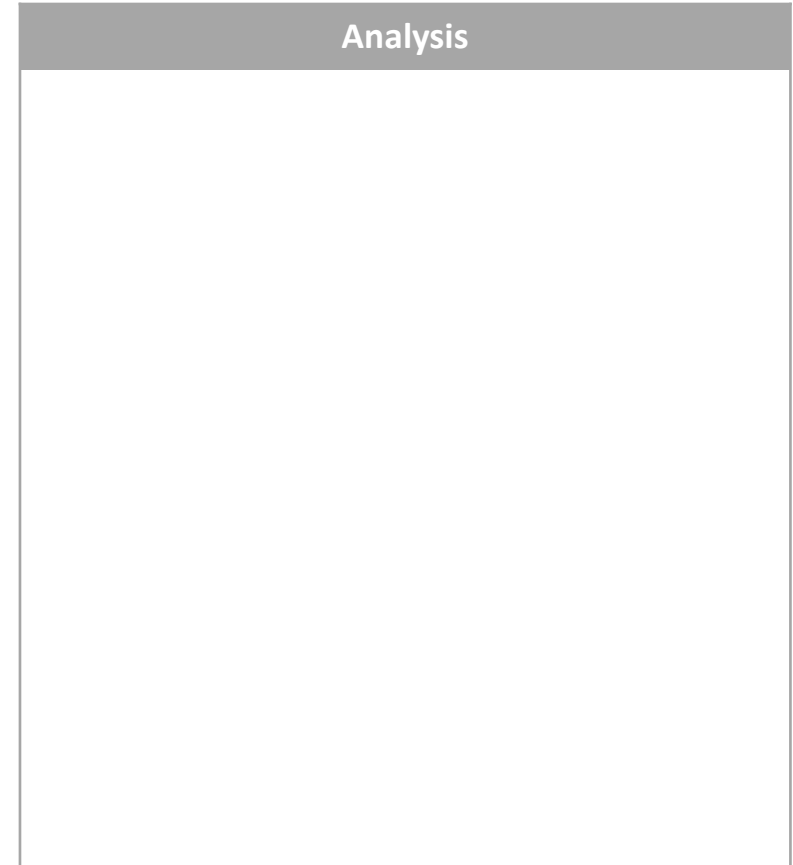
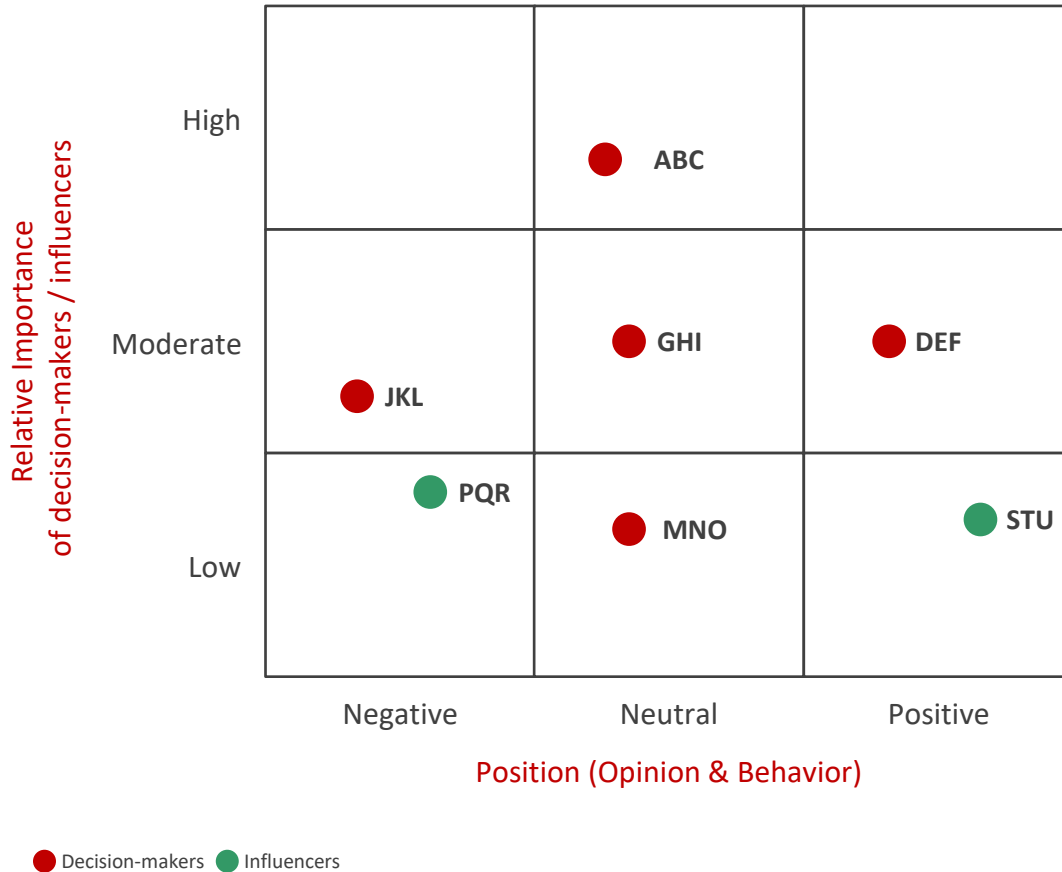
Sources: Smart Pharma Consulting

¹ Marketing Authorization – ² At EU level or national level, depending on the country and the product

This matrix which visualizes the importance and position of key stakeholders will help define and prioritize the target “customers” along the market access process

1 Market Access situation assessment – Stakeholders mapping

Illustrative



This table summarize the market access evaluation made by the decision-makers, by indication, for the brand¹ and its main competitors

1 Market Access situation assessment – Competitive landscape

Illustrative

	Marketing authorization	Clinical value	Economic value	System value	Reimbursement	Price	Rationale
Brand ¹							
Standard of Care (SoC)							
Competitor A							
Competitor B							

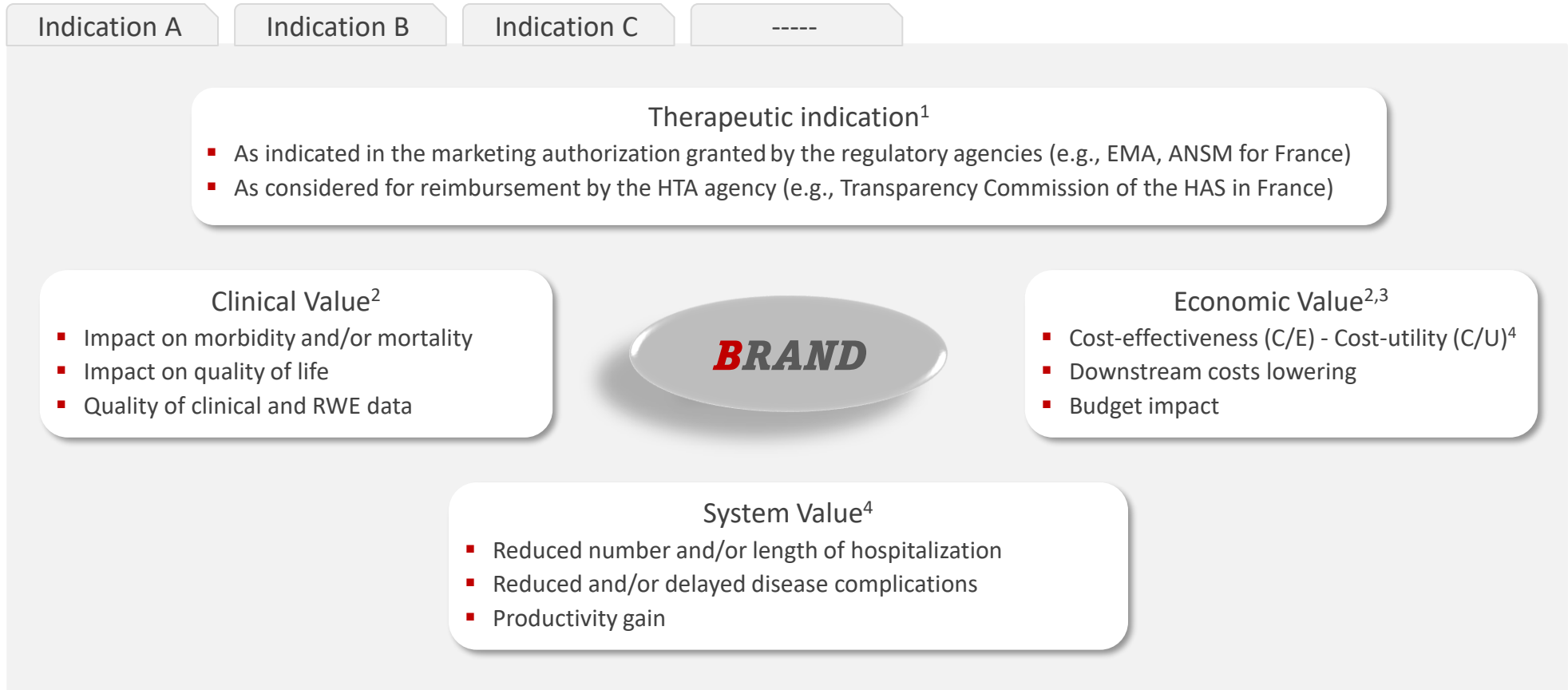
Sources: Smart Pharma Consulting

¹ If already evaluated by market access decision makers

The Brand Value Assessment per indication is either actual or intended, depending on whether the brand has already been assessed or not

1 Market Access situation assessment – Brand Value Assessment

Illustrative



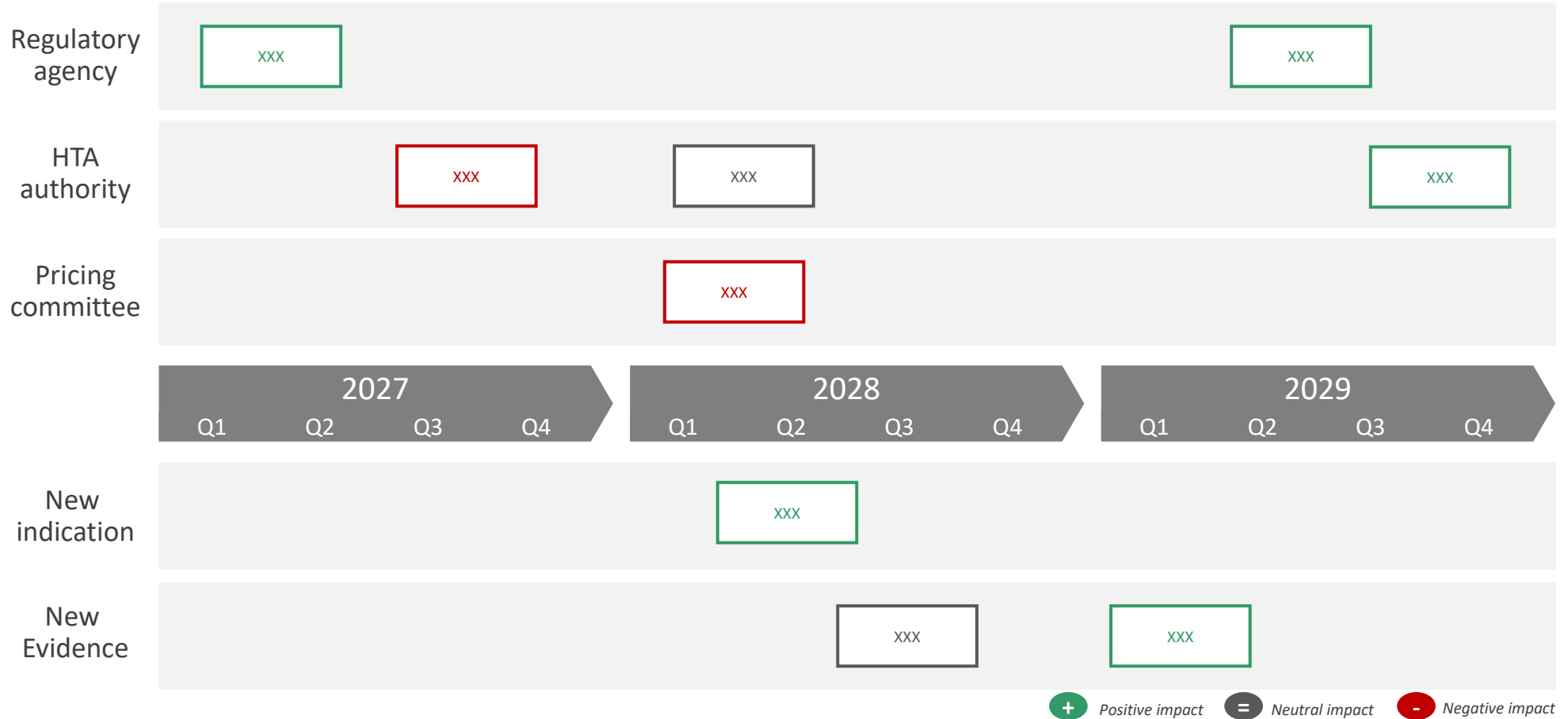
Sources: Smart Pharma Consulting

¹ Precising where the brand fits in the current therapeutic algorithm (i.e., line of treatment, subpopulation) –
² As estimated by the HTA agency – ³ In France, it is estimated by the CEESP – ⁴ Such as the Quality-Adjusted Life Year (QALY)

The indication of the key external and internal anticipated events and their impact (positive, neutral or negative) should be considered in the market access situation analysis

1 Market Access situation assessment – Key anticipated events

Illustrative



Sources: Smart Pharma Consulting

The “Advanced SWOT” helps the market access teams carry out a more specific and relevant assessment of the environment and the position of the brand

1 Market Access situation assessment – SWOT analysis

Advanced SWOT analytical tool

Access Opportunities	RI ¹	Access Threats	RI
<ol style="list-style-type: none"> 1. Epidemiology 2. Disease burden 3. Market access decision-makers 4. Influencers 5. Competitors 		<ol style="list-style-type: none"> 1. Epidemiology 2. Disease burden 3. Market access decision-makers 4. Influencers 5. Competitors 	
Brand Strengths	RI	Brand Weaknesses	RI
<ul style="list-style-type: none"> ▪ Therapeutic indications ▪ Value proposition ▪ Price & Reimbursement 		<ul style="list-style-type: none"> ▪ Therapeutic indications ▪ Value proposition ▪ Price & Reimbursement 	

The Advanced SWOT analysis represents a structured summary of the situation analysis from which key strategic drivers are drawn

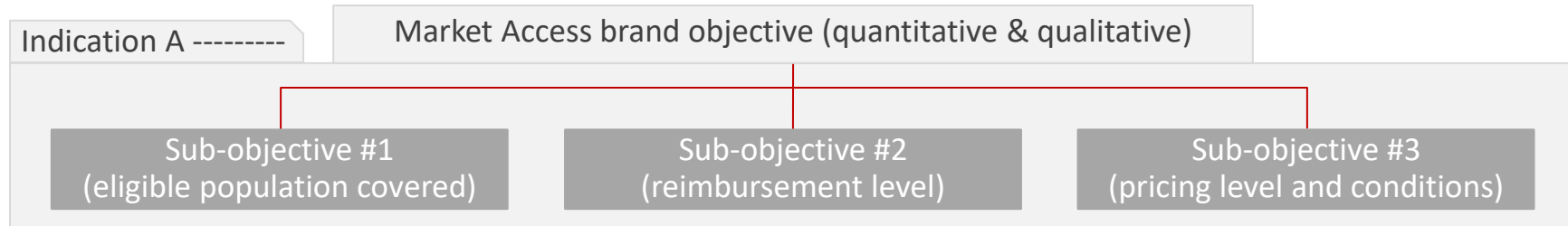
*“The Advanced SWOT has shown to be...
... a Smart Way Of Thinking”*

- To facilitate the crafting of the market strategic drivers, we recommend to use the “Advanced SWOT” which structures:
 - Market access environment **opportunities** and **threats** into its **five key determinants**:
 1. Epidemiology
 2. Disease burden
 3. Market access decision-makers...
 4. ... and their foreign and national influencers
 5. Competitors
 - Brand medical **strengths** and **weaknesses** into:
 - The **indication** (incl. line of treatment, eligible population, etc.)
 - The **value proposition** addressing unmet needs
 - The **price** (list and net prices, caping in volume and/or value, etc.) and **reimbursement** rate obtained...
... **by comparison** with key **competitors**
- The **items** listed in each of the four quadrants of the SWOT should be **evaluated** according to their **relative importance** (RI) by using a **five-point scale**

The market access objective, which can be split into sub-objectives, should be set by indication and articulated to maximize the brand value by decision-makers in patients' best interest

2 Market Access objective

Illustrative

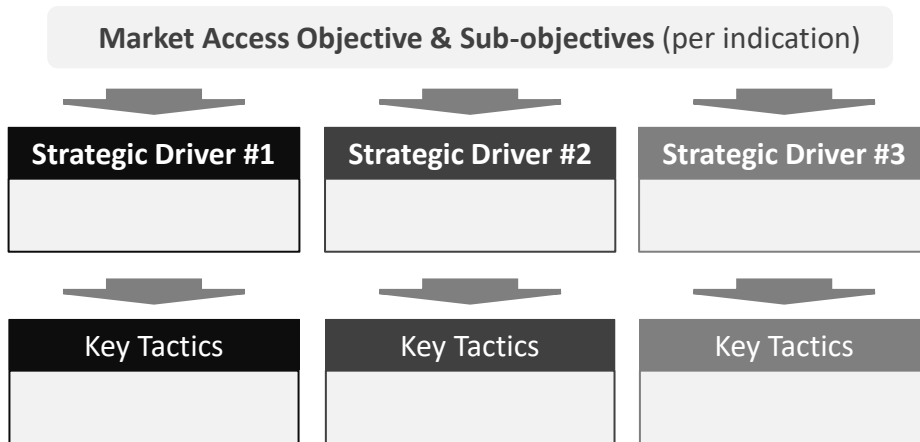


- Market access brand **quantitative** and **qualitative objective** and **sub-objectives** depend on:
 - The **market access environment** analysis
 - The assessment of the **brand per indication**
 - The **future events** re. the market access environment and the brand, as summarized in the “Advanced SWOT” analysis
- **Relevant** and **reliable** environment and brand **data** should be **gathered** to **set** the **objective** and **sub-objectives**
- The final **setting** of the **objective** and **sub-objectives** should **consider** the **likely impact** of key **tactics** to be implemented
- Market access brand **objective** and **sub-objectives** should be **set by indication**
- The following **sub-objectives** are **common examples**:
 - HTA agency**
 - Demonstrate clinically meaningful superiority vs. SoC
 - Get a reimbursement with no line-of-therapy restriction
 - Extend the population eligible for reimbursement
 - Obtain a reimbursement in line with or better than the SoC
 - Pricing committee**
 - Secure price consistent with EU reference countries
 - Get a net price above corporate floor price within y months
 - Limit mandatory rebates
 - Optimize price-volume agreements

The preferred strategic drivers are those enabling most likely to achieve the brand market access objectives and sub-objectives, considering the different indications of the company brands

3 Market Access strategic drivers (1/2)

The Market Access Brand Card



- The **strategic drivers**, derived from the “Advanced SWOT”, aim at achieving the set objectives and sub-objectives by:
 - **Seizing** market access environment **opportunities**
 - **Fighting** against market access environment **threats**
 - **Capitalizing** on Brand **strengths**, and/or
 - **Addressing** Brand **weaknesses**

- To achieve objective and sub-objectives (per indication) the **strategic drivers** will include the following components:
 - 1. Pricing & reimbursement strategy** (i.e., define price corridor, prepare and negotiate reimbursement dossier, optimize list price vs. net price (rebate, confidential discounts, MEA¹))
 - 2. Health Economics & Outcomes Research (HEOR)** evidence generation to justify the value of the product (i.e., develop C/E² models, localize global value dossiers, support submission with RWE, demonstrate medico-economic value vs. SoC)
 - 3. Manage HTA submissions** (build value dossiers, coordinate cross-functional inputs³, address HTA questions and challenges, prepare for oral hearings and/or expert committees)
 - 4. Stakeholder engagement** by building relationships with health authorities, payers and shaping the environment through scientific exchange, participation in policy discussion and collaborating with PAGs
- The **preferred strategic drivers are the most efficient and effective to achieve the objectives and sub-objectives** set
- **Consistency** between **objectives / sub-objectives**, **strategic drivers** and **key tactics** is **imperative**

Sources: Smart Pharma Consulting

¹ Managed Entry Agreements – ² Cost-Effectiveness models (e.g., budget impact models, Incremental Cost-Effectiveness Ratio or ICER – ³ From regulatory, medical, marketing departments, etc. at local level and with global functions

The Market Access Brand Card facilitates the alignment of objective and sub-objectives, strategic drivers and corresponding tactics, while ensuring complementarity with other functions¹

3 Market Access strategic drivers (2/2)

Illustrative

Market Access Brand Card			
Market Access Brand Objective & Sub-objectives			
Quantitative & Qualitative objectives & sub-objectives			
Strategic driver #1	Strategic driver #2	Strategic driver #3	Strategic driver #4
Key tactics	Key tactics	Key tactics	Key tactics

Complementarity & coordination with other key functions¹ of the pharma company

Sources: Smart Pharma Consulting

¹ Regulatory Affairs, Clinical Development department, Political and Government Affairs, Medical Affairs, Marketing, Sales, etc.

Each market access tactic should be carefully selected to best support the corresponding strategic driver and carefully planned to ensure a high-quality of execution

4 Market Access tactics & monitoring (1/3)

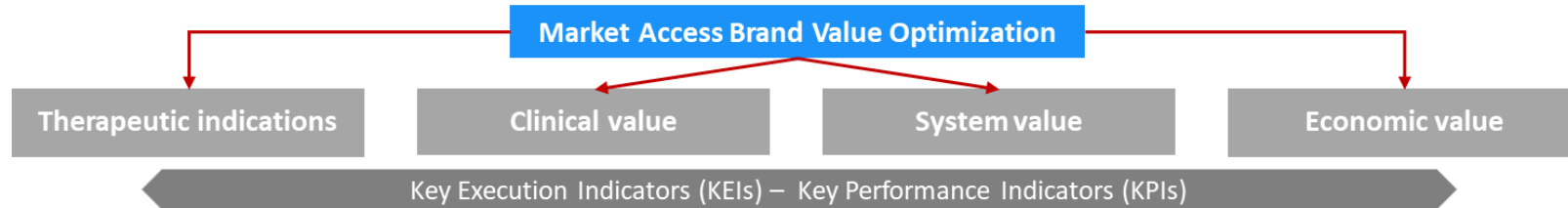


Table of key tactics related to a strategic driver

Strategic Driver <input type="text"/>					
Tactic / Activity	Objective	Target	Timing	Responsible	Budget

For each tactic, set a specific objective, precise the target concerned, plan it, name a responsible and estimate a budget

- Key **tactics** are the operational expression of strategic drivers which **contribute to achieve** the Market Access **Brand Value objective** and **sub-objectives** by:
 - Broadening the eligible population benefiting from the **therapeutic indications**, as defined by the HTA agency
 - Best leveraging evidence supporting the **clinical value**
 - Objectifying the positive **effect** on the **healthcare system**
 - Measuring the **budget neutrality** or **savings**
- Before **selecting a tactic**:
 - The magnitude of its **impact** and its level of **feasibility** should be **evaluated**
 - It may be needed to **test the idea** with a specific tool¹

Sources: Smart Pharma Consulting

¹ See the one shown in our position paper “Excellence in Execution” p. 1840 – <https://smart-pharma.com/wp-content/uploads/2026/01/Smart-Pharma-2016-2025-Collection.pdf>

KEIs¹ and KPIs² are both essential, the first type of indicators measuring the quality of execution and the second one the degree of objective achievement

4 Market Access tactics & monitoring (2/3)

Table of key tactics with monitoring indicators

Strategic Driver						KEIs ¹	KPIs ²
Tactic / Activity	Objective	Target	Timing	Responsible	Budget		

Examples of monitoring indicators

Quantitative	
<ul style="list-style-type: none"> % alignment of clinical endpoints with HTA expectations Number of patients enrolled in RCTs and /or RWE studies at national level Budget impact modelling (x€/year) <p style="text-align: center;">KEIs</p>	<ul style="list-style-type: none"> HTA assessment rating (SMR-ASMR)³ Reimbursement level (0% to 100%) % of eligible population covered Achieved vs. target net price Price-volume clause terms <p style="text-align: center;">KPIs</p>
Qualitative	
<ul style="list-style-type: none"> Pre-submission meeting with HTA Population definition optimization Completeness of the pricing dossier Quality of interactions with the pricing committee while negotiating 	<ul style="list-style-type: none"> End-point validation Robustness of economic models Quality of value dossier Corporate reputation as perceived by market access decision-makers

Our recommendations

- Select a limited number of metrics to measure:
 - The quality of execution of tactics with **KEIs**
 - The business outcome of tactics with **KPIs**
- By **measuring the quality of execution and the impact of market access tactics**, it is possible **to adjust the market Access Brand Plan** (during the year or from the previous year) **to make them more efficient and effective**

“KEIs check that you are on the right track and KPIs check that you arrive at destination”

Sources: Smart Pharma Consulting

¹ Key Execution Indicators – ² Key Performance Indicators – ³ SMR (clinical benefit) and ASMR (clinical added value) as assessed by the HAS (the French HTA agency)

This proposed Activity Card includes, on one page, a planning section and a monitoring section for each market access tactic

4 Market Access tactics & monitoring (3/3)

Illustrative

Market Access Activity Card

<ul style="list-style-type: none"> Market Access strategic drivers: precise the driver the tactic should support Market Access objective: define the specific objective of the tactic Description: describes briefly the tactic 		<ul style="list-style-type: none"> Stakeholder types: internal, external (e.g., KOLs, payers, PAGs) Number of stakeholders: 		Importance M – H*		
Planning	Actions			Timing	Owner	FTE / OpEx
Key activities corresponding to the medical tactic	1.			•	•	•
Monitoring	Quantitative / qualitative metrics	Indicator objective	Indicator achievement		Key implications / Comments	
Key Execution Indicators (Quality of execution)	•	•	•		•	
Key Performance Indicators (Impact of the activities)	•	•	•		•	

Sources: Smart Pharma Consulting

* M = Medium – H = High

Smart Pharma Service Offering

Consulting Services

- Smart Pharma Consulting is well-known for its ability to help access, medico-marketing and sales teams build robust brand plans
- To date, Smart Pharma consultants have helped **40 pharma** companies develop strategic and tactical plans for more than **85 brands** across **20** different **therapeutic areas**
- Thus, we can bring our **support** to address the following issues:
 - Which **Market Access environment analyses** to carry out?
 - How to define **key success factors** and the corresponding **challenges** with the help of the “**Advanced SWOT**”?
 - How to **develop** Market Access environment and brand **scenarios**?
 - How to **set** Market Access brand **objectives** and **sub-objectives**?
 - How to **select** the **strategic drivers** to achieve the Market Access brand objectives and sub-objectives?
 - How to support the strategic drivers by **tactic** likely to **strengthen** the **positive opinion** of **stakeholders** for the **brand**?
 - How to **anticipate** the **impact** of **future Market Access activities** and **investment** options on the brand value?
 - How to **monitor the quality** of **execution** and the **impact** of **Market Access investment decisions** and **activities**?

Training Program

Example of a One-Day Program¹

- 8:30 Introduction to the program
- 8:40 Concepts, methods and tools related to Market Access Brand Plans
- 9:00 **Module 1:** Situation analysis of the Market Access environment by indications of the brand
Stakeholders’ need, opinion and behavioral analysis
- 10:30 *Break*
- 10:50 Advanced SWOT analysis
- 12:00 **Module 2:** Market Access brand objectives / sub-objectives
- 13:00 *Lunch*
- 14:00 **Module 3:** Crafting Market Access strategic drivers
- 15:00 **Module 4:** Market Access tactics selection
- 16:00 *Break*
- 16:20 **Module 5:** Market Access tactics monitoring
- 17:20 Conclusion and key takeaways
- 17:30 End of the program

Target Audience

- Collaborators from Market Access departments, involved in the development of Market Access Brand Plans, whatever their level of responsibility and seniority

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

Best-in-class Series

- This series intends to provide practical tools and recommendations to enhance the efficacy and efficiency of the most important activities or processes in place within pharma companies
- Our tools and recommendations are based on both:
 - Our consulting experience in the pharma sector
 - Our research for innovative, pragmatic and useful solutions
- Each issue is designed to be read in less than 20 minutes

National Market Access Brand Plans Recommendations for Affiliates

- The quality of Market Access Brand Plans are often sub-optimal due to a weak building process and a lack of time and understanding of the benefits that can be drawn from such an exercise
- We propose a structure, a method and practical tools to facilitate the building of best-in-class Market Access Brand Plans
- Such Brand Plans have shown to enhance the efficiency and efficacy of Market Access activities carried out to support the brand

*“High-Performance Market Access Brand Plans
require method, rigor and pragmatism”*

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 activities in advanced masters
 - Training activities for pharma executives
 - The publication of articles, booklets, books and expert reports

- Our publications can be downloaded from our [website](#):
 - 43 articles
 - 85 position papers covering the following topics:
 1. Market Insights
 2. Strategy
 3. Market Access
 4. Medical Affairs
 5. Marketing
 6. Sales Force Effectiveness
 7. Management & Trainings
- Our research activities in pharma business management and our consulting activities have shown to be highly synergistic
- We remain at your disposal to carry out consulting projects or training seminars to help you improve your operations

Best regards

Jean-Michel Peny