

# Medical Affairs Best Practices...

————— MEDICAL SERIES —————

... in a Changing Environment

June 2023

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**The purpose of this position paper is to analyze strategic, tactical and organizational best practices of Medical Affairs departments in a changing environment**

## ***CONTEXT***

- Over the past decade, Medical Affairs have moved from a support function providing medical information...
- ... to a strategic function collecting insights to direct R&D to better fulfill unmet needs and...
- ... disseminating scientific and medical data to take the best advantage of innovations

## ***OBJECTIVE***

- Provide information about the evolving mission and organization of Medical Affairs departments
- Share thoughts re. Medical Affairs strategic planning and implementation
- Make recommendations likely to improve the contribution of Medical Affairs to value creation for patients, HCPs and Pharma companies

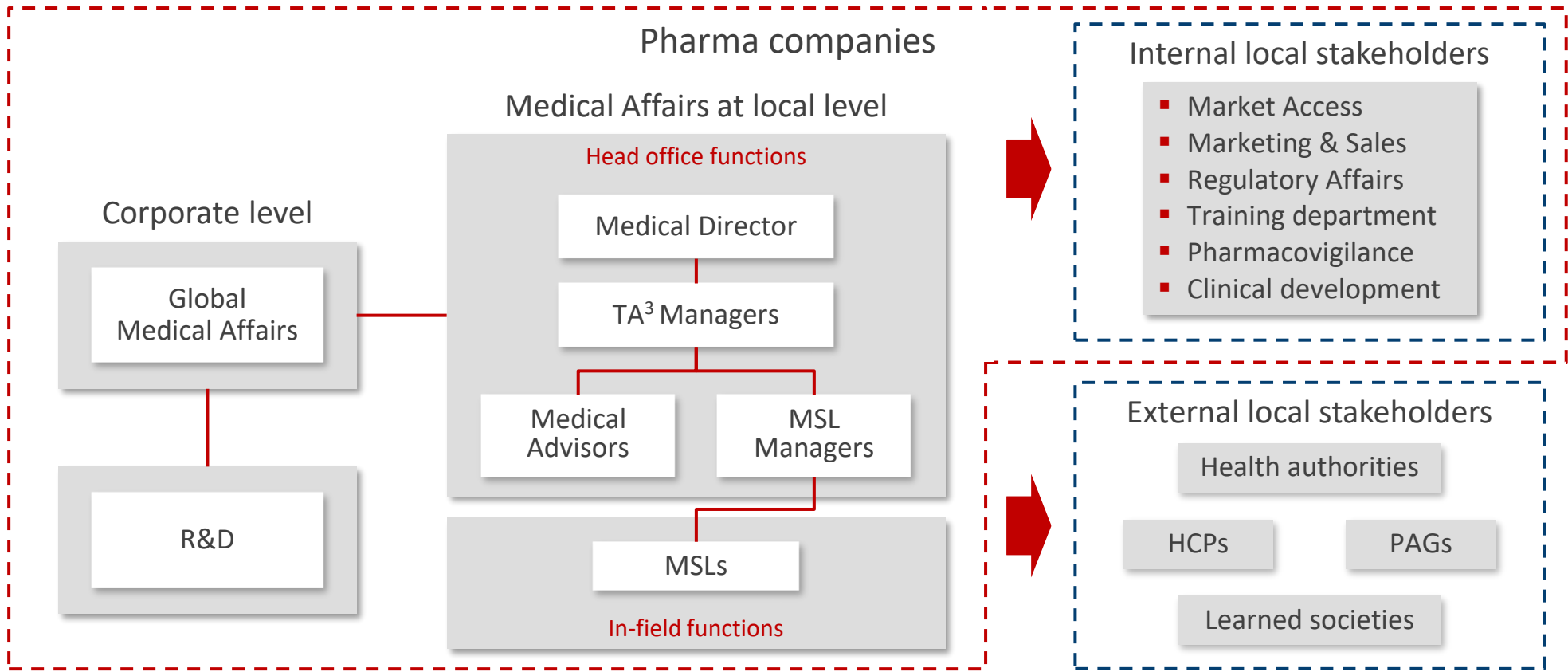
## ***METHOD***

- The content of the position paper is based on:
  - Desk research carried out in May 2023
  - Smart Pharma Consulting experience and previous publications related to medical topics
  - Selected interviews with senior executives from Pharma companies' Medical Affairs department

Medical Affairs are at the crossroads of pharma companies, interacting internally with all operational functions; and externally with health authorities, HCPs<sup>1</sup>, PAGs<sup>2</sup> and learned societies

Medical Affairs positioning

Illustrative

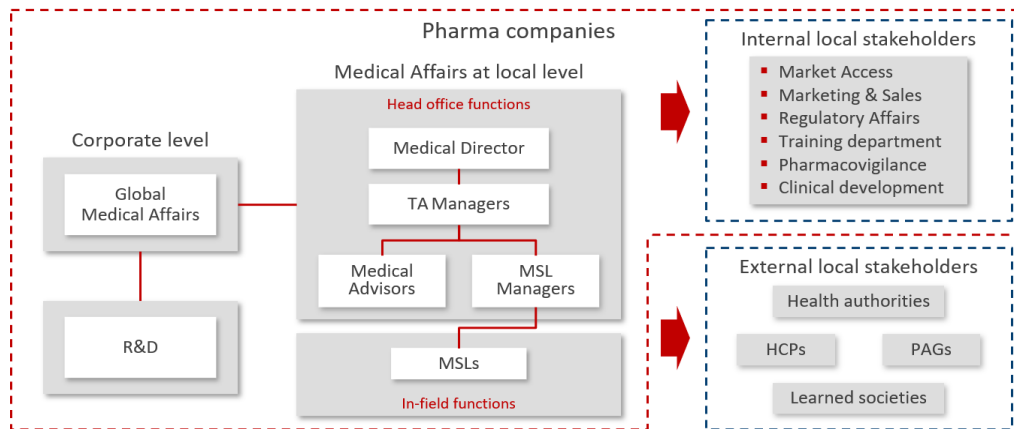


Sources: Smart Pharma Consulting analyses

<sup>1</sup> Especially KOLs – <sup>2</sup> Patient Advocacy Groups – <sup>3</sup> Therapeutic Area

# Medical Affairs guarantee a two-way communication to align R&D programs with medical needs and to favor the optimal use of marketed brands by generating supportive evidence

## Medical Affairs mission (1/2)



**Insights gathering**  
Gathering of insights re. medical needs from which they will craft a medical strategy to direct and contribute to prioritize the pharma company R&D programs

**Data generation & dissemination**  
Generation and dissemination of medical and scientific data to help HCPs optimize disease management with the company's drugs by supporting their proper usage

**Medical education**  
Knowledge sharing and education of internal and external stakeholders throughout products lifecycle:

- Early-development: to raise KOLs interest
- Pre-launch: to build awareness and position the product
- Launch: to educate on clinical evidence and product use
- Post launch: to provide CME (Continuing Medical Education)

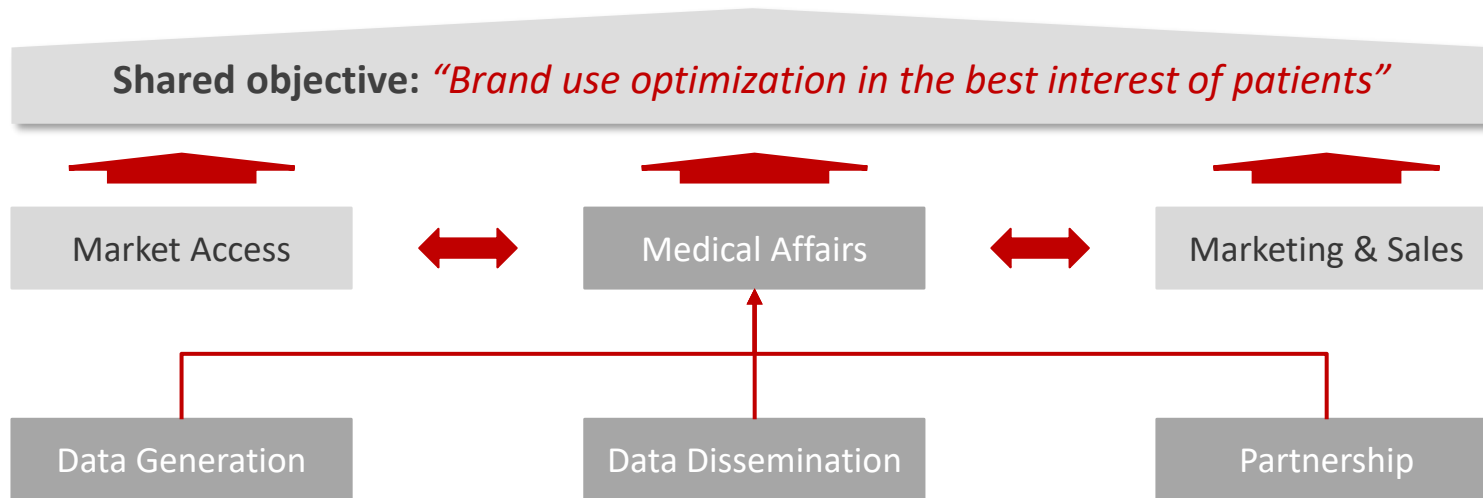
**Scientific platform development**  
Development of a living document<sup>1</sup>, regularly updated, to ensure that disease state and drug information are consistently and optimally communicated

Sources: "Medical Affairs Strategy - Four responsibilities", www.vintura.com – "Four Cornerstones of Pharma Medical Affairs" by L. Dezzani (2021) – Smart Pharma Consulting analyses

<sup>1</sup> Cross-functional process led by Medical Affairs but involving other departments of pharma companies (HEOR<sup>2</sup>, market access, marketing & sales<sup>3</sup>, regulatory affairs, pharmacovigilance, clinical development, etc.) – <sup>2</sup> Health Economics and Outcomes Research – <sup>3</sup> Including med reps, key account managers, key institution managers

## Medical Affairs activities should contribute to optimize the use of pharma companies' brands by HCPs in the best interest of patients

### Medical Affairs mission (2/2)

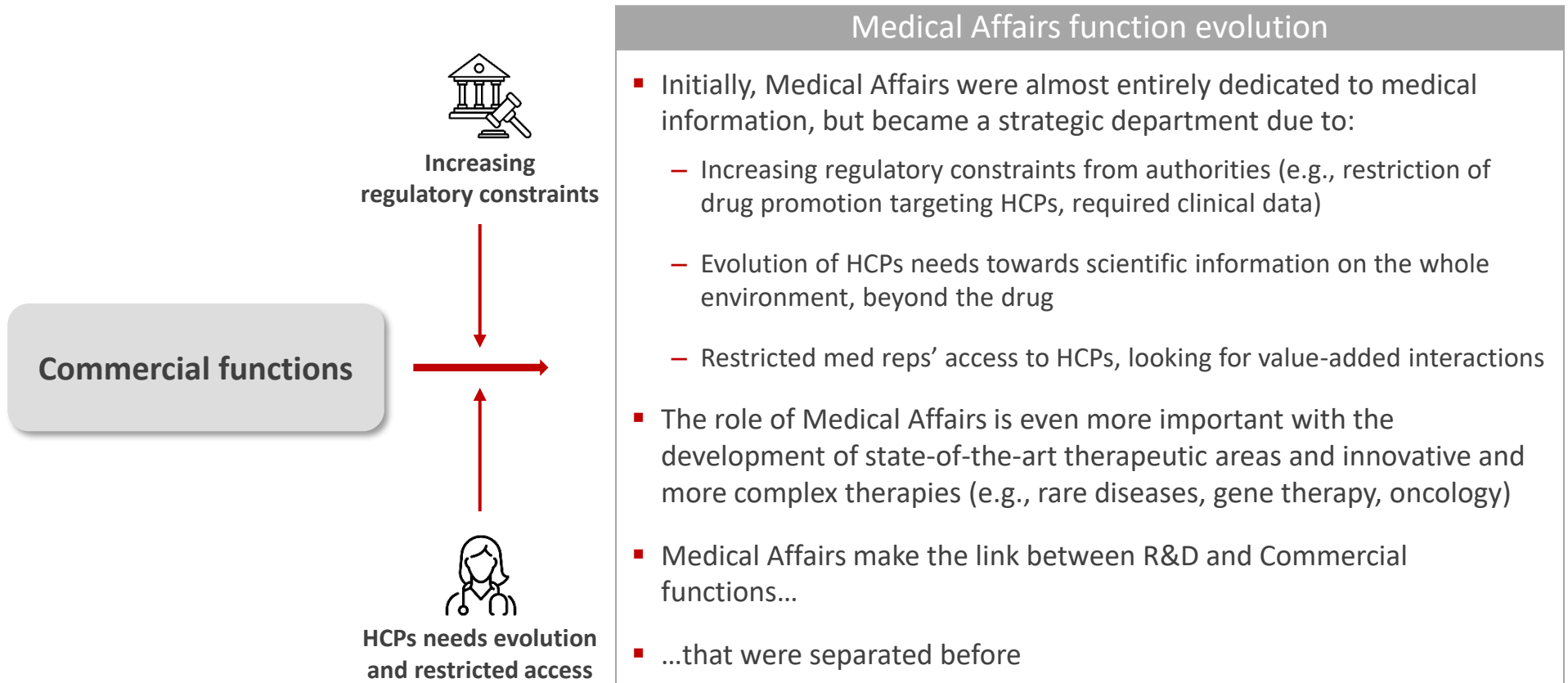


- Medical Affairs play a central role in supporting internal<sup>1</sup> company stakeholders to fulfill the needs of external ones<sup>2</sup> on medical aspects re.:
  - Disease management
  - Specific indications
  - Brands

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

# The role of Medical Affairs has evolved into an independent and pillar function mainly due to the increasing pressure from authorities, and evolving expectations and practices of HCPs

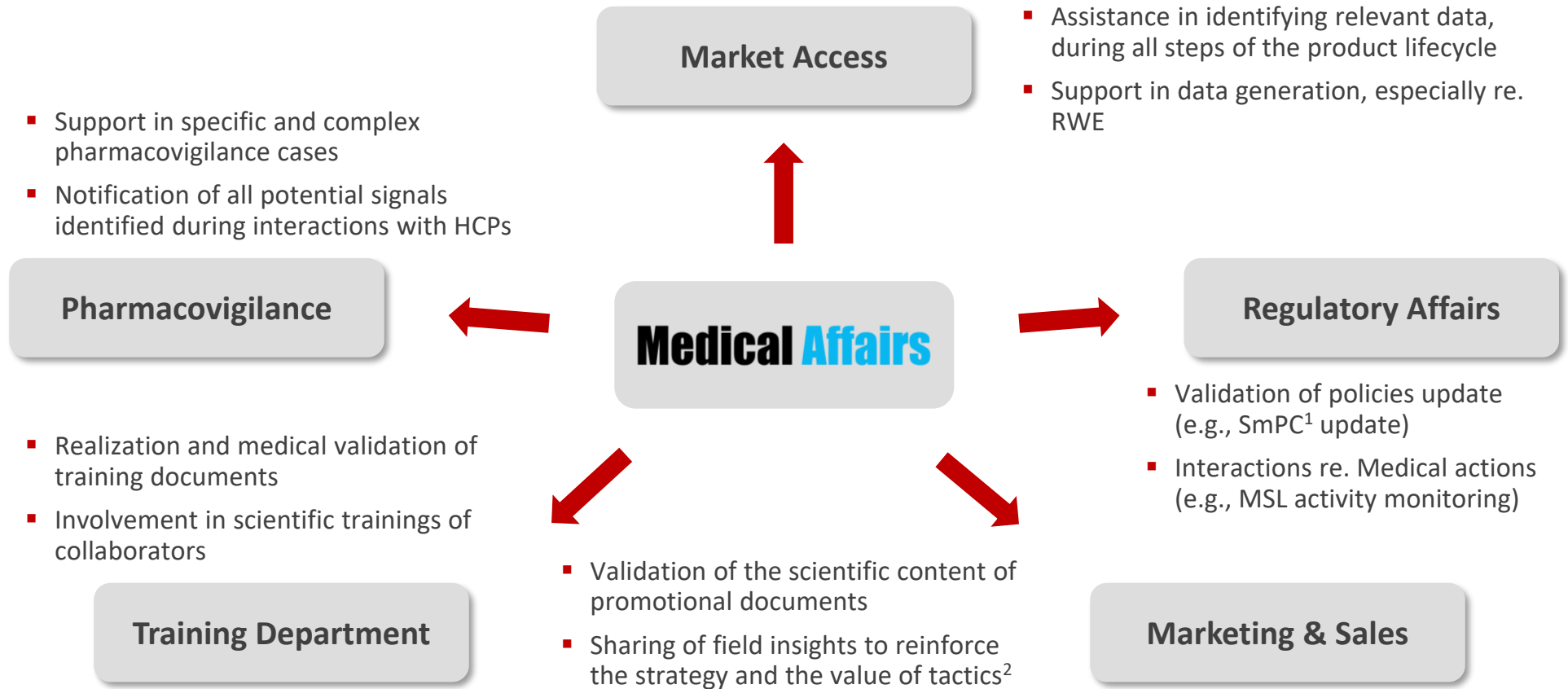
## Shift of Medical Affairs interactions with other affiliate departments



Sources: "Medical Affairs: its role and added value within pharmaceutical industry", C. Picard (2021) – The role of Medical Affairs in moving from R&D to Commercialization (2013) – Smart Pharma Consulting analyses

## Medical Affairs have a cross-functional role and act as a true scientific platform and partner, for all key internal departments

### Interactions with internal local stakeholders

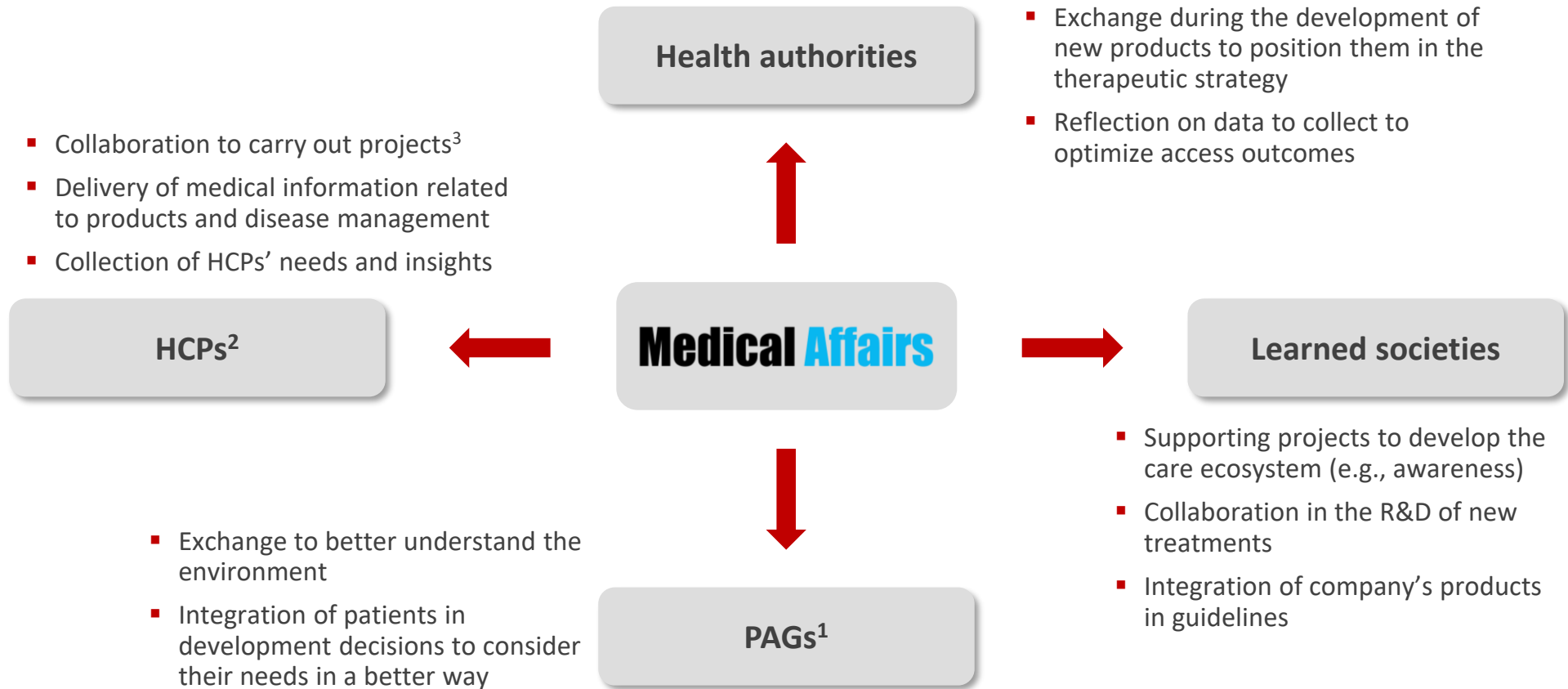


Sources: "Medical Affairs: its role and added value within pharmaceutical industry", C. Picard (2021) – Complete guide on pharmaceutical medical affairs, Viseven (2022) – Smart Pharma Consulting analyses

<sup>1</sup> Summary of Products Characteristics – <sup>2</sup> Especially while developing brand plans

## Medical Affairs have an essential role to play towards key external stakeholders, whether in product and disease knowledge collection, management, and delivery

### Interactions with external local stakeholders



Sources: *The role of medical affairs in positive and appropriate engagement with PAGs* (Openhealth group 2022) – “Medical Affairs: its role and added value within pharmaceutical industry”, C. Picard (2021) – Smart Pharma Consulting analyses

<sup>1</sup> Patient Advocacy Groups –<sup>2</sup> Especially KOLs –  
<sup>3</sup> E.g., Investigator-initiated study, speakers at congress, advisory board



# Medical Advisors play a key role within Medical Affairs by ensuring the downward alignment of the global medical strategy at national level and providing local insights to Global Medical Affairs

## Medical Advisor role

### Mission

- The Medical Advisor is the scientific and medical expert of a pathology, its environment and related treatments
- He ensures the accuracy and the relevance of the scientific and medical data that are collected and disseminated

### Activities with internal stakeholders

- Ensure a two-way communication w/ Global Medical Affairs
- Develop a national medical strategy formalized in a plan
- Propose scientific and medical data to be used for marketing authorization and/or value dossiers
- Identify non-interventional studies to fulfill a need
- Validate the scientific content of promotional materials
- Develop training documents and train collaborators
- Provide expert opinion re. pharmacovigilance cases
- Validate the update of SmPCs<sup>1</sup> made by Regulatory Affairs
- Support MSLs (i.e., training, content, strategy sharing)

### Activities with external stakeholders

- HCPs**

  - Support HCPs to carry out research projects<sup>2</sup>
  - Interact during congresses, symposia and other meetings<sup>3</sup>
- Health authorities**

  - Select data to position scientifically new drugs in the therapeutic strategy in the context of market access
- Learned societies**

  - Collaborate on projects to improve patient screening, diagnosis, therapeutic choices, therapeutic adherence, etc.
- Patient Advocacy Groups (PAGs)**

  - Gather PAGs needs to define projects to fulfil patient needs

Sources: "Medical Affairs: its role and added value within pharmaceutical industry", C. Picard (2021) – Smart Pharma Consulting analyses

<sup>1</sup> Summary of Products Characteristics – <sup>2</sup> Such as collaborative studies or Investigator-Initiated Studies – <sup>3</sup> HCPs can also be selected by Medical Advisors to participate to advisory boards, to give lectures, etc.

# MSLs are the field team of Medical Affairs in pharma companies, who are dedicated to the development of relationships with KOLs and to high-level scientific communications

## Medical Science Liaison (MSL) role

### Mission

- The Medical Science Liaison (MSL) is field-based in a designated territory where he focuses on building non-promotional relationships with KOLs and other HCPs
- He is allowed to discuss off-label indications re. drugs on HCPs' demand

### Activities with internal stakeholders

#### Global Medical Affairs

- Translate the global medical strategy at its territory level
- Coordinate the execution of research projects by KOLs<sup>1</sup>
- Gather medical insights from the field<sup>2</sup>

#### Marketing & Sales

- Develop an action plan complementing the med reps' one
- Answer questions and train on scientific environment
- Co-organize local scientific events<sup>3</sup>

#### KAMs<sup>4</sup> & KIMs<sup>5</sup>

- Provide medical data to support hospital listing process
- Provide medico-economic data re. company's drugs

### Activities with external stakeholders

#### HCPs

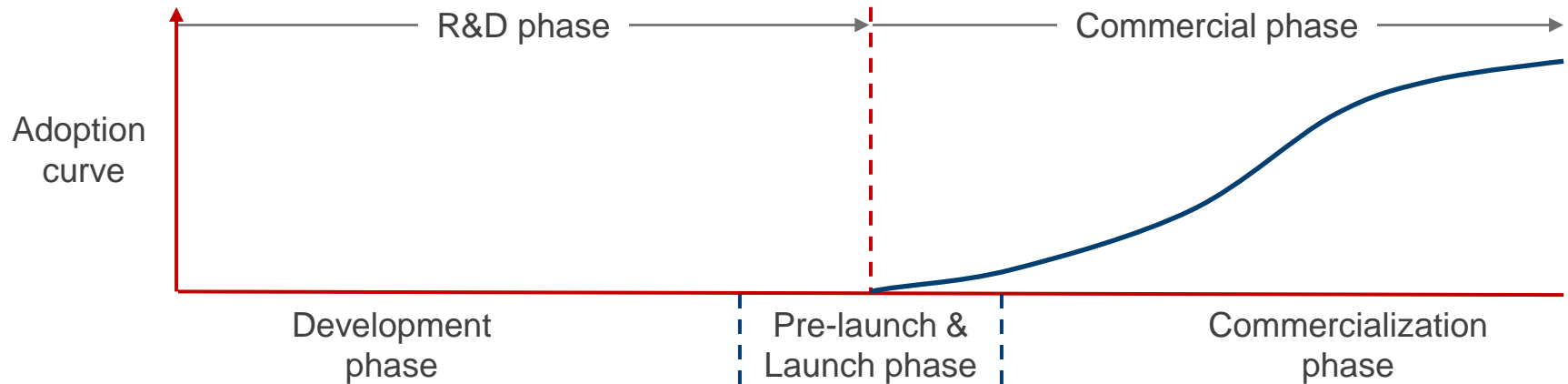
- Map and target KOLs to raise their interest for new drugs
- Identify high potential centers and investigators for company-sponsored clinical studies
- Support studies implementation jointly with CRA<sup>6</sup>
- Collect insights re. medical needs, drug use and competition
- Contribute to medical education of HCPs for better drug use
- Respond to HCPs requests re. clinical development, RWE studies, Investigator-Initiated Studies (IIS)
- Interact with HCPs during congresses, symposia and other meetings, such as advisory boards

Sources: "Medical Affairs: its role and added value within pharmaceutical industry, C. Picard (2021) – "The changing role of the modern MSL", Pharmaceutical Market Europe, October 2015 – Interviews with 5 MSLs – Smart Pharma Consulting analysis – Smart Pharma Consulting analyses

<sup>1</sup> Collaborative studies or Investigator-Initiated Studies – <sup>2</sup> E.g., KOLs needs, frequent medical questions / objections – <sup>3</sup> Such as staff meetings in hospital departments, medical meetings, webinars – <sup>4</sup> Key Account Managers – <sup>5</sup> Key Institution Managers who interact with regional health authorities and payers – <sup>6</sup> Clinical Research Associates

**Medical Affairs play an essential role to ensure that clinical development will fulfill patient unmet needs and that health authorities, payers and HCPs will make the best use of marketed drugs**

**Medical Affairs activities along the drug lifecycle**



Medical Affairs  
key activities



- Proactive insight gathering re. unmet medical needs...
- ... to translate science into clinical practice
- Identification of clinical and medico-economic meaningful differentiators

- Insight gathering
- Clinical and medical data dissemination
- KOL identification/mapping
- Participation to ad boards
- Management of early access programs (EAP)

- Contribution to RWE and economic data generation & dissemination
- Participation to ad boards
- Preferred contact point of KOLs to support IIS<sup>1</sup>
- Internal & external training

Sources: Smart Pharma Consulting analyses

<sup>1</sup> Investigator-Initiated Studies

## The use of digital technology in clinical trials facilitates patient recruitment and retention, reduces associated costs and generates real-world evidence

### Medical Affairs digitalization: Clinical data generation



#### Real-world evidence generation

- **Digital tools** represent an opportunity to generate **real-world evidence** and thus strengthen patient's role to assess drugs value and to design innovative products
- Their development has been facilitated by rapid advances in technology<sup>1</sup>
- The generation of these data offers a better understanding of real-world care pathway with the help of **new indicators** such as:
  - PROMs (Patient-Reported Outcomes Measures)
  - PREMs (Patient-Reported Experience Measures)...
- ...enabling to **evaluate the quality of care** as perceived by patients

#### Case study: VERKKO trial application

- A **Phase IV trial** has been launched, **fully digitally** using a connected blood glucose meter, by Sanofi in collaboration with Mendor and eClinicalHealth
- 60 patients recruited via **Facebook** with an **81% conversion rate** (recruitment/application), which is better than typical recruitment results
- The digitalization of the study resulted in a:
  - High **patient satisfaction**
  - **Reduced coordination time** by 2/3
  - **Patient-centered** study design

Sources: eClinicalHealth Announces Successful Results for an Entirely Remote Online Clinical Trial (Businesswire 2016) – From recruiting to data collection, the impact of connected digital health in clinical trials (Nadir Ammout 2016) – Smart Pharma Consulting analyses

<sup>1</sup> Smartphones, tablets, electronic medical records, big data analysis through AI, etc.

## Digital tools and channels offer a wider choice of innovative ways to deploy medical communication strategy and have changed the profile of KOLs

### Medical Affairs digitalization: Medical communication

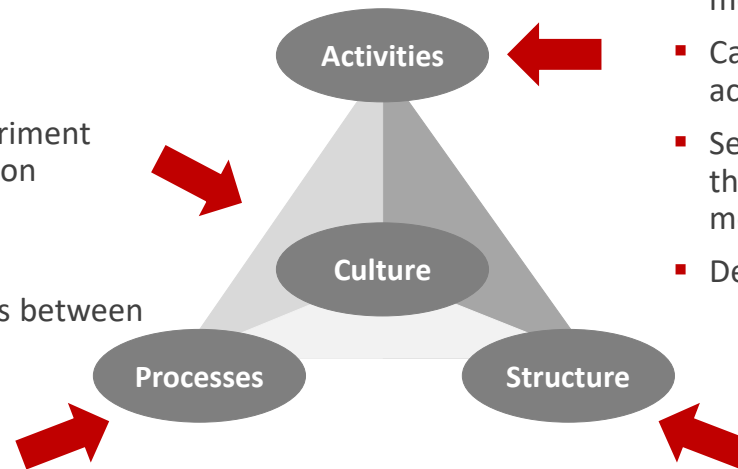
Digital channels	Content personalization	KOL / DOL
<ul style="list-style-type: none"> <li>▪ Use of innovative formats to communicate with HCPs (e.g., chatbots, podcasts, webinars) is increasing</li> <li>▪ Digitalization of MSL activities and interactions with KOLs has become increasingly important</li> <li>▪ Post-Covid-19, 66% of KOLs surveyed by the MSL Society indicated that they preferred to use digital tools over face-to-face visits with MSLs</li> <li>▪ Thus, more and more MSLs and medical advisors adopt an omnichannel approach with KOLs</li> </ul>	<ul style="list-style-type: none"> <li>▪ As for medical reps, AI-based tools provide a better understanding of HCPs' needs (e.g., habits, learning preferences)...</li> <li>▪ ...and advanced analysis of interactions allows to propose the most engaging and impactful content for HCPs</li> <li>▪ Digital tools are particularly useful to disseminate specific data to KOLs because they facilitate the identification, collection, storage and structure of scientific and medical information</li> </ul>	<ul style="list-style-type: none"> <li>▪ The emergence of digital channels has changed the landscape of medical influencers:               <ul style="list-style-type: none"> <li>– DOLs (Digital Opinion Leaders) who have an influential role in sharing medical information on social networks, coexist with...</li> <li>– KOLs, knowing that less than 30% of the latter have a social media presence</li> </ul> </li> <li>▪ Ideally, companies will identify experts that combine the strengths of traditional and digital thought leaders and develop relationships with the most relevant of them</li> </ul>

*Sources: Transforming Medical Affairs: Tapping the alchemy of storytellers and digital start-ups (McKinsey 2019) – Medical Affairs Digitization (PharmExec.com 2021) – Digital Medical affairs with a human touch – To maximize KOL impact, Medical Affairs needs a digital strategy too (PharmaSpectra resources 2021) – How to digitalize MSL teams for increased efficiency (Pharmafield) – Medical affairs: Key imperatives for engaging and educating physicians in a digital world (McKinsey 2018) – Smart Pharma Consulting analyses*

## The Medical Affairs organization should be designed and adjusted to best support the implementation of the medical strategy crafted by the pharma company

### Key organizational dimensions to be leveraged

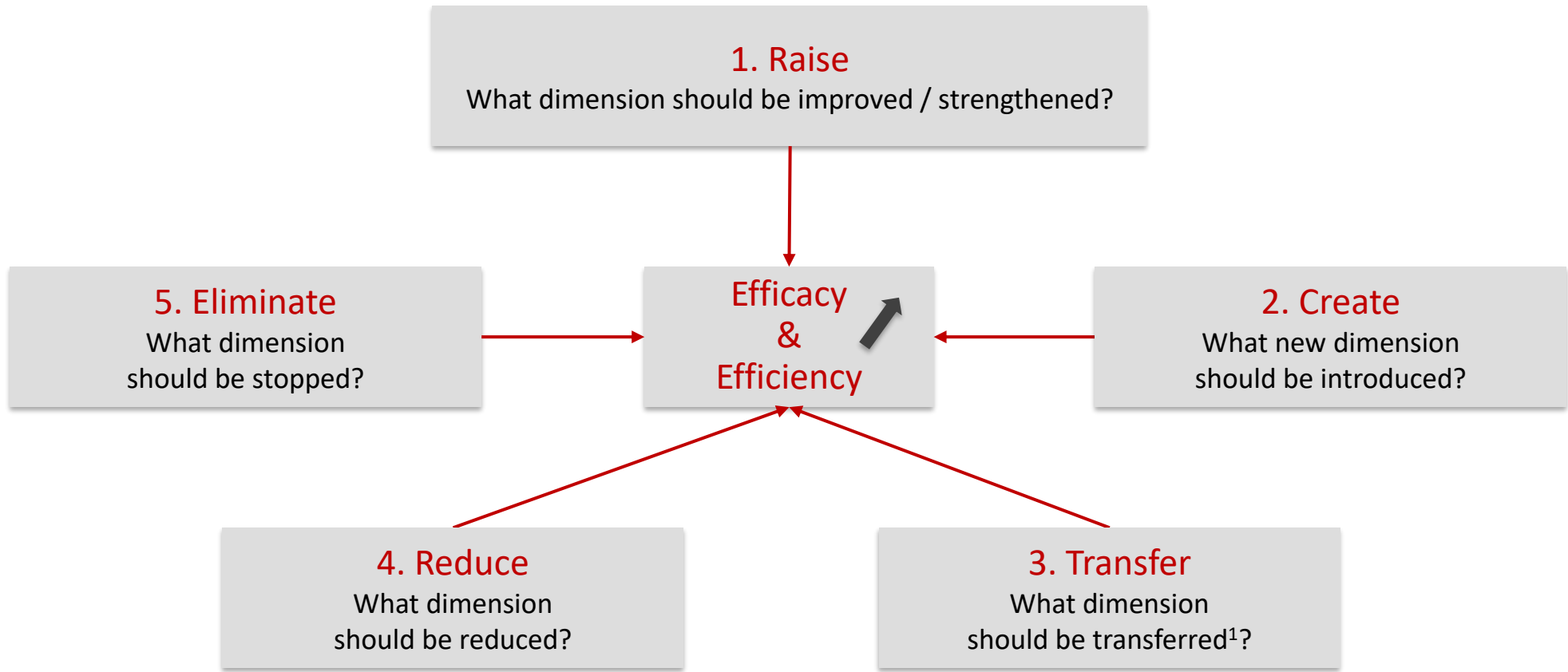
- Develop a culture of superior stakeholder satisfaction
- Develop a powerful vision so that collaborators feel connected<sup>1</sup>
- Install a participative culture<sup>2</sup>
- Engrain a culture of excellence
- Encourage pro-activity, agility and experiment to find new solutions to excel in execution
- Facilitate cross-functional collaborations between Medical Affairs and other departments
- Develop tools to:
  - Align objective, strategy and tactics
  - Measure the quality of execution and the impact of activities
  - Reinforce the cohesion of teams
  - Learn from experience
- Streamline processes and set up standards of excellence



- Provide direction and resources for achieving medical strategic objectives
- Focus on activities that best support the medical strategy
- Carefully plan the execution of key medical activities
- Select a limited number of metrics to monitor the quality of execution and the impact of medical activities
- Develop the skills of collaborators
- Design an adaptative structure
- Set up a flat and lean organizational chart
- Simplify structures by eliminating needless complexity
- Delineate lines of command and decision rights

When applied to Medical Affairs departments, the five following actions can help improve their organizational efficacy and efficiency

How to leverage key organizational dimensions?



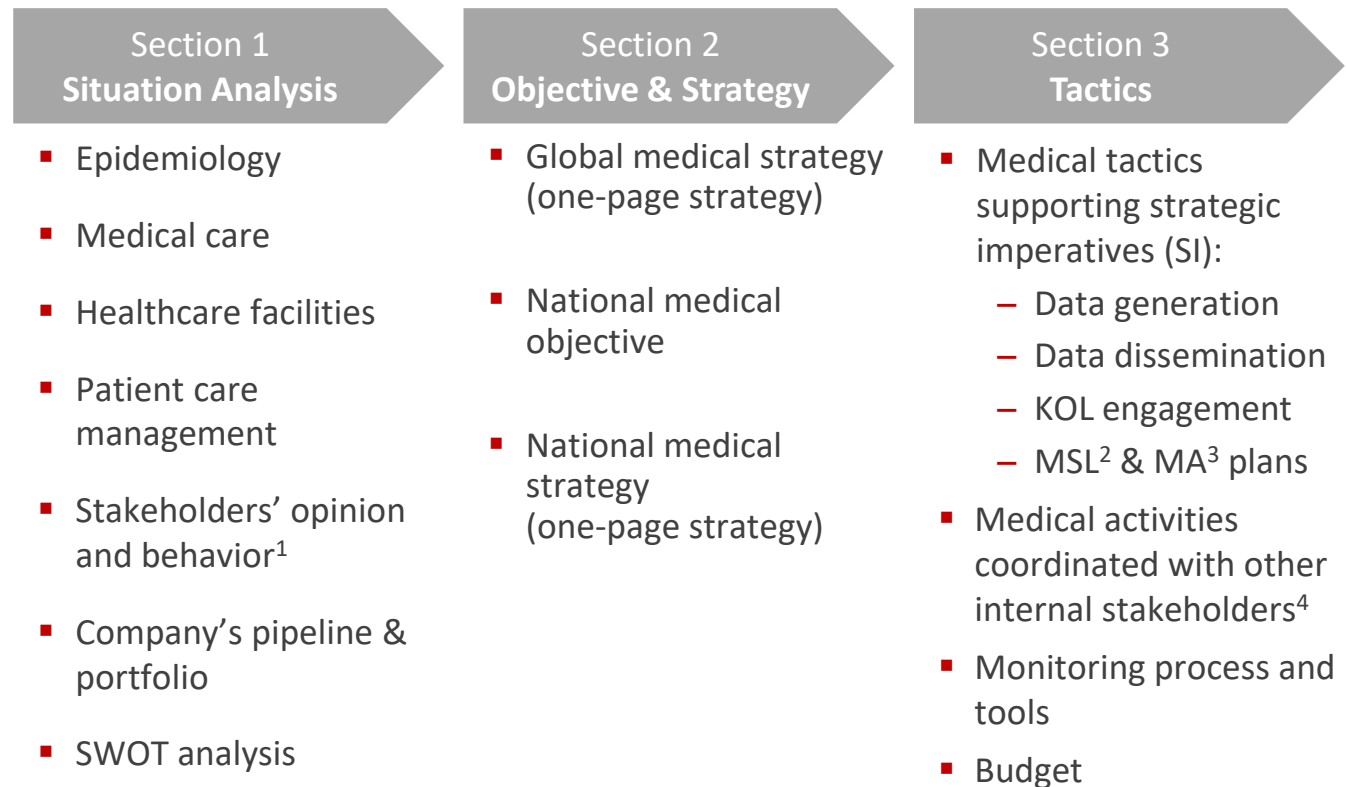
Sources: Smart Pharma Consulting adapted from Blue Ocean Strategy by W. Chan Kim and Renée Mauborgne (2005)

<sup>1</sup> To another department, colleague or outsourced

## The purpose of Strategic Medical Plan is to allocate the right medical resources to reach the medical objective set, in an effective and efficient way

### Strategic medical plan – Structure

Conventionally, strategic medical plans are structured in three sections





## High-Performance Strategic Medical Plans require method, rigor and pragmatism

### Strategic medical plan – Recommendations

#### Recommendation #1

Analyze – don't just describe the medical situation

#### Recommendation #2

Carry out a structured and fact-based Medical SWOT analysis

#### Recommendation #3

Craft a medical strategy enabling to meet the set medical objective

#### Recommendation #4

Select key medical activities to support the crafted medical strategy

#### Recommendation #5

Integrate indicators to monitor activity execution and corresponding impact

# Medical Affairs will evolve in their activities with the development of digital tools but also, in their role which is becoming increasingly central and essential within the pharma industry

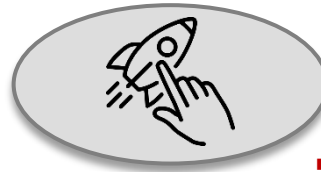
## What is the future of Medical Affairs?

### Insights Management

- Use of conventional and digital scientific data sources (e.g., publications, social listening, connected devices) and...
- ...capitalization on digital tools (e.g., algorithms, AI) to generate and analyze HCPs and patient insights that are valuable to direct pharma companies' R&D programs, and deliver relevant medical information

### Scientific Evidence Generation

- New digital tools allow to generate RWE data...
- ...which are more and more requested by health authorities and valuable for pharma companies
- Science, safety and transparency are the key drivers of Medical Affairs and a clear governance strategy for new tools must be established



### Medical Affairs Transformation

- Medical Affairs are becoming a “Pillar function” oriented towards patients' life improvement as a whole and not only focusing on drugs
- Therefore, several new roles are emerging to fulfill this function (e.g., patient officers)
- In addition, technologies are expanding beyond-the-pill to improve patient care (e.g., DTx<sup>1</sup>)

### Stakeholders Engagement

- Medical Affairs are at the crossroads of stakeholders (e.g., HCPs, PAGs<sup>2</sup>, health authorities)
- Thus, they must determine best value-added strategies to engage stakeholders and develop sustainable relationships
- Patient-centric initiatives are increasing, with patients engaged as soon as product development

Sources: Medical Affairs: A pillar function in transformation (BearingPoint) – 4 Medical Affairs trends for 2023 and beyond (2022) – Smart Pharma Consulting analyses

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

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

## Medical Series

- The Medical Series covers different topics related to Medical Affairs, either at Corporate or Affiliates level
- Depending on issues, Smart Pharma Consulting shares:
  - Strategic, tactical and organizational thoughts and recommendations
  - Well-documented facts and figures, including outcomes of recent benchmarking studies
  - Practical methods and tools
- Each issue is designed to be read in 15 to 20 minutes and not to exceed 24 pages

## Medical Affairs Best Practices... ... in a Changing Environment

- The purpose of this position paper is to analyze strategic, tactical and organizational best practices of Medical Affairs departments
- Thus, we provide insights and recommendations re. Medical Affairs:
 

<ul style="list-style-type: none"> <li>– Positioning</li> <li>– Mission</li> <li>– Interactions with internal and external stakeholders</li> <li>– Drug lifecycle activities</li> </ul>	<ul style="list-style-type: none"> <li>– Digitalization of activities</li> <li>– Leverage of key organizational dimensions</li> <li>– Strategic medical plan</li> <li>– Future</li> </ul>
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## 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 (ESSEC B-school, Paris Faculty of Pharmacy)
  - Training activities for pharma executives
  - The publication of articles, booklets, books and expert reports
- Our publications can be downloaded from our website:
  - 41 articles
  - 67 position papers covering the following topics:
 

1. Market Insights	5. Marketing
2. Strategy	6. Sales Force Effectiveness
3. Market Access	7. Management & Trainings
4. Medical Affairs	
- 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