



# **Medical Science Liaisons**

## **- A New Strategic Lever -**

***Recommendations to Boost MSLS' Performance***

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## Introduction

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**This position paper outlines the role of MSLs and proposes strategic and operational recommendations to boost their performance, while also complying with regulations**

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### Context & Objective

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- **Medical Science Liaisons (MSLs) play a pivotal role to maintain a close relationship with KOLs (Key Opinion Leaders), also called TLs (Thought Leaders) who are instrumental in:**
  - Developing new products through their collaboration in pre-clinical and / or clinical trials
  - Raising the awareness and the preference of HCPs (Health Care Professionals) but also of health authorities, PAGs (Patient Advocacy Groups), individual patients, etc., for their products
  
- **The increasing role of MSLs results mainly from:**
  - New molecular entities that are becoming more and more complex...
  - ... and that are mainly prescribed by specialists who are less and less inclined to meet medical reps
  - Increasing regulatory constraints
  
- **In this position paper, Smart Pharma Consulting:**
  - Analyzes the current role and responsibilities of MSLs<sup>1</sup>
  - Proposes a process, tools and...
  - Makes strategic recommendations...

**... to boost MSLs' performance**

# 1. MSLs' current role & responsibilities

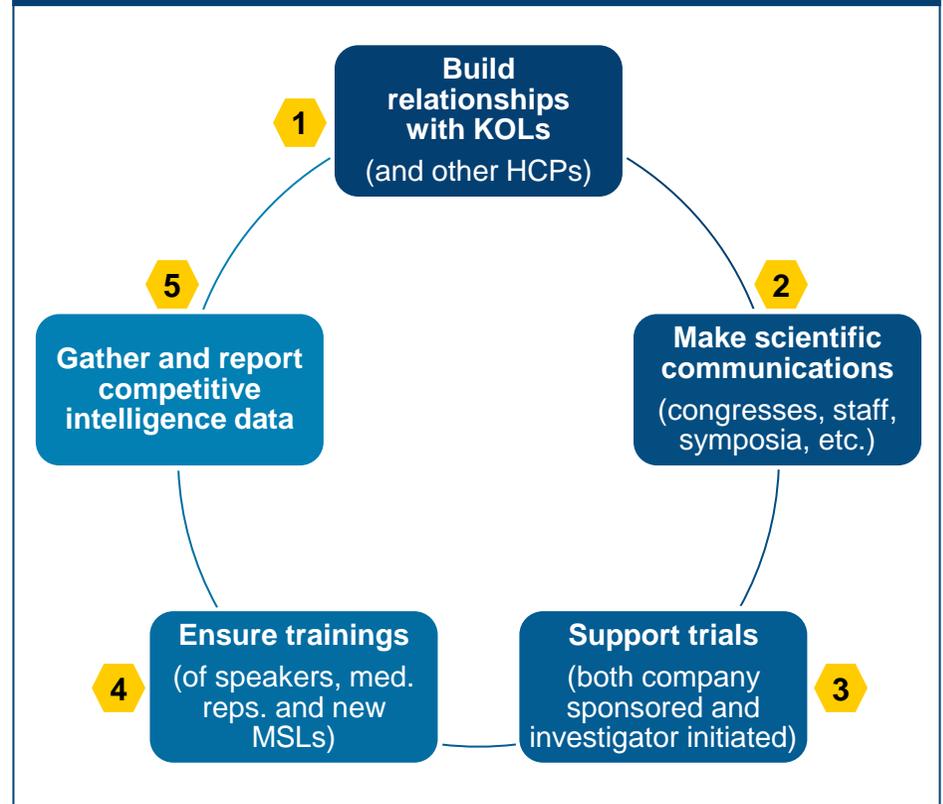
MSLs are the field team of medical affairs in pharma companies, who are dedicated to the development of relationships with KOLs and to high-level scientific communications

## Overview

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

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

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



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

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

# 1. MSLs' current role & responsibilities

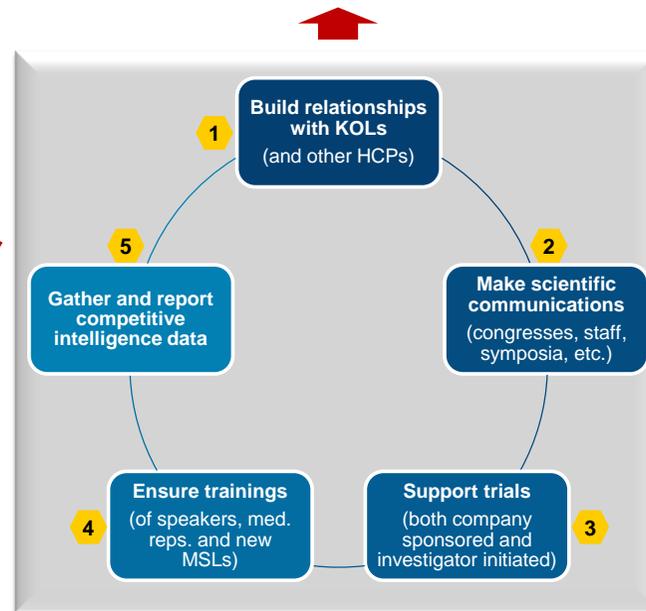
MSLs are often asked to cover a large scope of activities in collaboration with both internal and external stakeholders

## MSLs' detailed core activities

- Identification, selection and collaboration with KOLs: setting-up of boards, organization and participation in scientific information meetings, development of continuous medical education (CME) projects, patients or physicians associations funding, etc.
- Management of Investigator Initiated Studies (IIS)<sup>1</sup>: requests processing and follow-up
- Invitations to congresses / symposia, etc.

- Presence in congresses and attendance to competitors' presentations
- Desk research: on competitors, on therapeutic areas and critical review of scientific papers
- Medico-economic research

- Training of med. reps. and certifications
- Training of other functions, such as marketing, in some companies
- Training of speakers communicating on companies' products / therapeutic areas, etc.
- Writing of supports for FAQ&O<sup>2</sup>



- Answers to certain HCPs' medical questions (through med. reps.)
- Participation in scientific information meetings (staffs, face to face, etc.) for on- and off-label indications, therapeutic area and pipeline
- Presentation of studies in congresses / symposia

- Identification of needs and demands of KOLs for IIS
- Identification of high potential centers and investigators for company-sponsored clinical trials
- Support for studies implementation and follow-up jointly with Clinical Research Associates (CRAs)

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

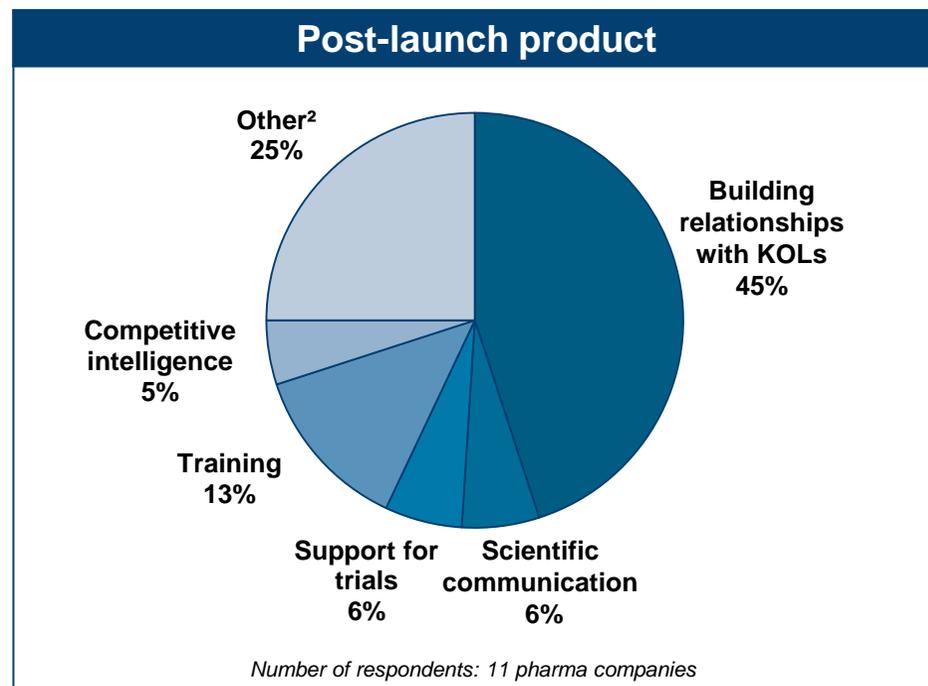
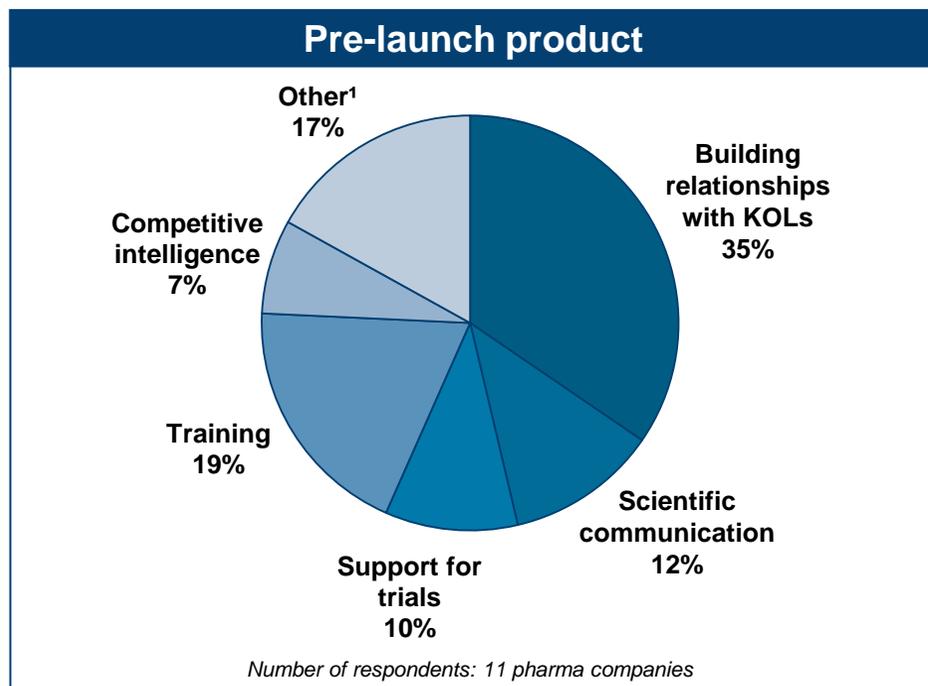
<sup>1</sup> Also called: Investigator-Initiated Trials or IIT – <sup>2</sup> Frequently Asked Questions & Objections

# 1. MSLs' current role & responsibilities

Building relationships with KOLs and training HCPs or colleagues account together for ~55% to 60% of MSLs' activity in both pre- and post-launch settings

## MSLs' time allocation per core activities

MSLs share the same core activities from one company to another, but there could be important variabilities in planning and duties



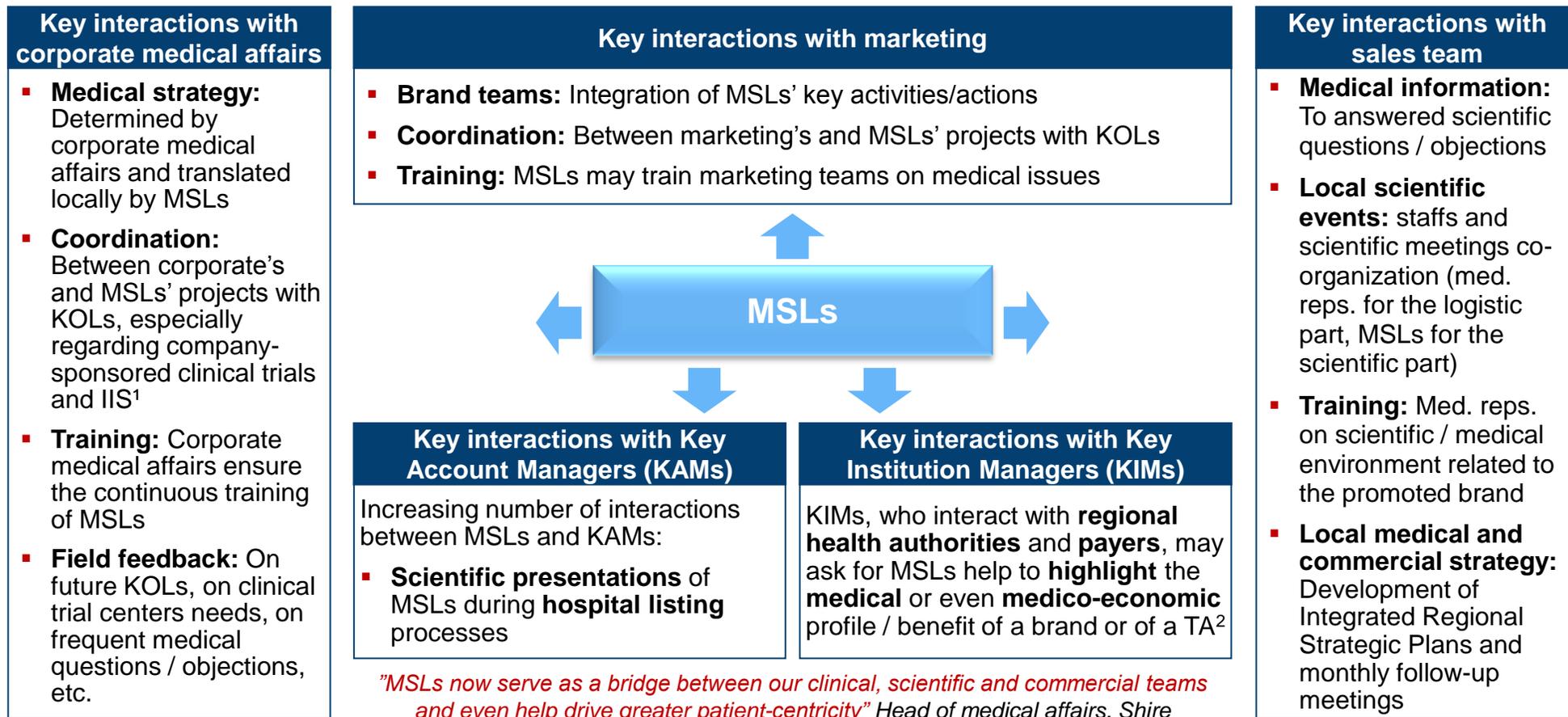
Sources: "Aligning the Activities and Goals of Medical Science Liaison Teams for Strengthened Corporate Sustainability", MSL World – Interviews with 5 MSLs – Smart Pharma Consulting analysis

<sup>1</sup> Including pre-launch transversal activities with marketing or medical teams, etc. –  
<sup>2</sup> Including support to other field forces, participation in internal advisory boards, etc.

# 1. MSLs' current role & responsibilities

**MSLs must support KIMs who facilitate regional market access of brands, KAMs who ensure their listing at hospital level and marketing and sales reps who promote them**

## The transversal role of MSLs



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

<sup>1</sup> Investigator Initiated Studies – <sup>2</sup> Therapeutic Area

# 1. MSLs' current role & responsibilities

**MSLs are not allowed to promote products, however, they can discuss their off-label use from an objective perspective and in response to a demand from HCPs**

## Compliance issues regarding MSLs

### Current situation analysis

- The main mission of MSLs is to build collaborative relationships with KOLs and to facilitate the exchange of unbiased scientific information between them and the company
- Unlike medical representatives, MSLs are not allowed to promote their company's products...
- ... but can exchange unrestrictedly unbiased scientific information regarding the products and the related therapeutic areas
- MSLs' activities are not subject to specific laws or regulations
- Like any other employees of the company they belong to, MSLs are supposed to comply with:
  - International and national regulations
  - The industry codes of practice
  - The accepted standards of best practice
  - The company's compliance procedures

### Focus on off-label prescription

- Off-label prescription is a common practice, particularly in fields where the approved treatments do not provide satisfactory results (e.g. oncology, psychiatry) or for a subset of the patients population, such as children
- Under certain circumstances, and according to more or less well-defined procedures, depending on the country, it is allowed for physicians to prescribe some products off-label (e.g. Early Access Programs<sup>1</sup> in Europe or Expanded Access Programs in the USA)
- Off-label promotion by pharmaceutical companies is banned
- In practice, if KOLs or other HCPs ask questions regarding off-label indications, MSLs should respond factually
- It is not recommended for MSLs to pro-actively communicate about off-label indications, even if the communication is based on scientific evidence, this could be considered as disguised promotion
- To protect their corporate reputation and their own employees and to prevent to be fined, companies such as Bristol-Myers Squibb have written SOPs<sup>2</sup> that clarify the Do's and Don'ts in terms of compliance for employees, including for MSLs

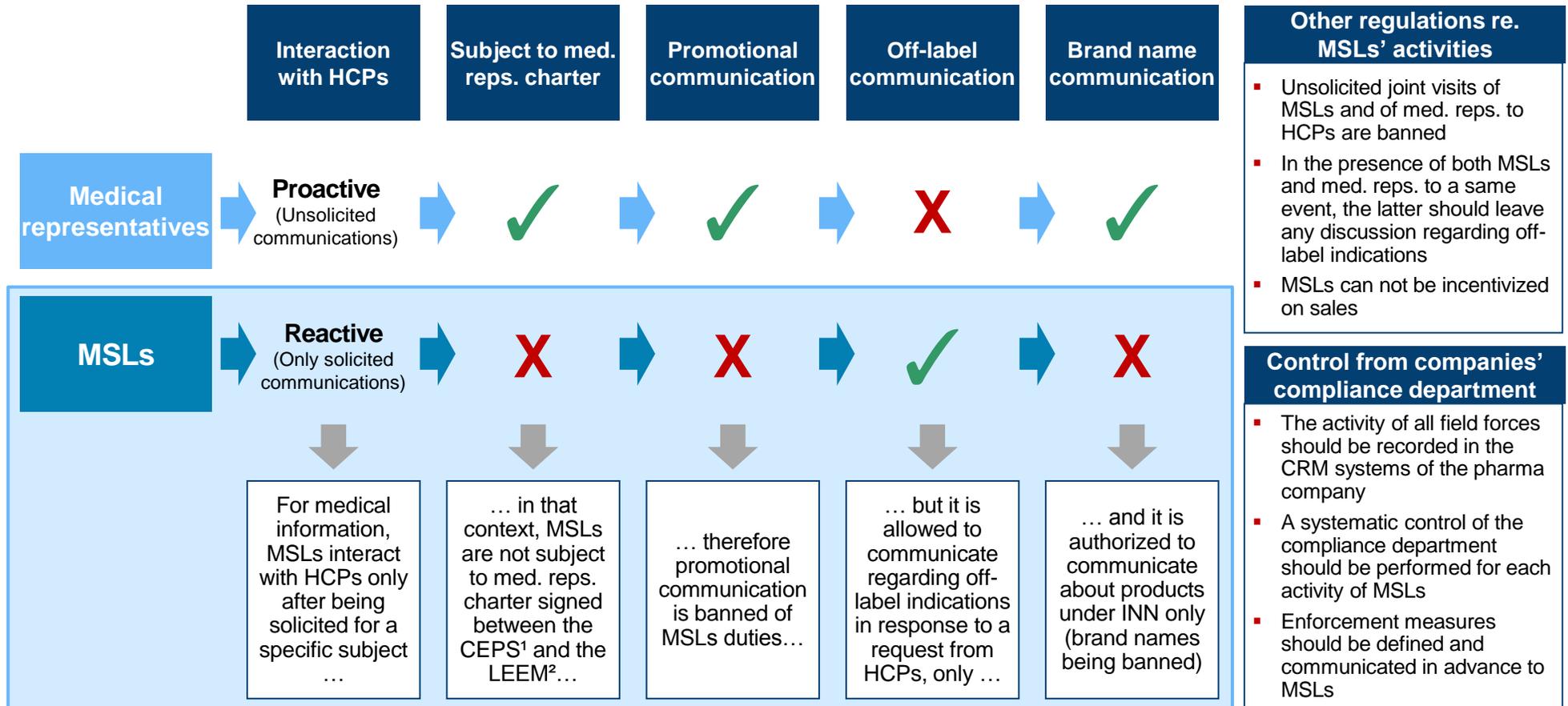
Sources: "MSL-KOL Engagement", FirstWord Dossier June 2011 – MSL Institute – Smart Pharma Consulting analysis

<sup>1</sup> Two types: Compassionate Use Programs (CUPs) or Named-Patient Programs (NPPs) – <sup>2</sup> Standard Operating Procedures

# 1. MSLs' current role & responsibilities

In general, MSLs' activity is not regulated by dedicated texts and they are not subject to the same restrictions as medical representatives

## Regulatory framework relative to MSLs' activities – The French case



Sources: Charte de la visite médicale, October 2014 – Interviews with 5 MSLs – Smart Pharma Consulting analysis

<sup>1</sup> CEPS: French drugs prices regulation authority – <sup>2</sup> LEEM: French pharma companies association – <sup>3</sup> INN: International Nonproprietary Names

# 1. MSLs' current role & responsibilities

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

## Six main issues facing MSLs teams

	Key issue	What to do?
1	<b>Distinction from sales / marketing</b> <ul style="list-style-type: none"> <li>Role confusion persists in the mind of some HCPs / KOLs</li> </ul>	<ul style="list-style-type: none"> <li>Information campaigns should be implemented to inform stakeholders of the distinctive role of MSLs</li> <li>The information should be provided through calls</li> </ul>
2	<b>Disconnection with corporate initiatives</b> <ul style="list-style-type: none"> <li>Initiatives initiated by corporate (clinical trials, etc.) are not always well coordinated with MSLs teams</li> </ul>	<ul style="list-style-type: none"> <li>The coordination should be improved by implementing standard communication processes and rules</li> </ul>
3	<b>Distraction from core activities</b> <ul style="list-style-type: none"> <li>MSLs, for being well trained and effective professionals, can contribute to tasks such as health economics, outcomes research, etc.</li> </ul>	<ul style="list-style-type: none"> <li>A clear definition of MSLs' responsibilities should be made to all internal stakeholders through information campaigns and the objectives for each of them should be quantified in MSLs' action plans</li> </ul>
4	<b>Extensive geographical zones</b> <ul style="list-style-type: none"> <li>MSLs teams are small; therefore they have to cover large geographic areas and must undertake frequent travels</li> </ul>	<ul style="list-style-type: none"> <li>The use of alternative communication technologies such as web conferencing, e-mailing, teleconferences, etc., should be considered</li> </ul>
5	<b>Complex regulatory environment</b> <ul style="list-style-type: none"> <li>Government agencies keep on scrutinizing on how products are promoted by pharma companies</li> </ul>	<ul style="list-style-type: none"> <li>Pharma companies should focus on MSLs' compliance...</li> <li>... which should be carefully monitored</li> </ul>
6	<b>Trend towards specialization</b> <ul style="list-style-type: none"> <li>The development of secondary care products and the increasing complexity of science lead to major training requirements for MSLs</li> </ul>	<ul style="list-style-type: none"> <li>Pharma companies should keep on investing on their MSLs' scientific training</li> </ul>

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

# 1. MSLs' current role & responsibilities

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

## MSLs' challenges – Required skills – Expected outputs

### MSLs' challenges

- Keeping up with the **latest scientific information**
- Building strong and sustainable **relationships with KOLs**
- Managing **multiple and diversified tasks**
- Complying with **national regulations** and **internal code of conducts**
- Ensuring effective **coordination with collaborators**

### Required skills

- Excellent **scientific knowledge** and **understanding** to carry out peer-to-peer discussions during interactions with KOLs
- Strong **communication skills** to properly position:
  - A company's therapeutic expertise
  - A given product at pre- or post-launch stage
- Ability to **manage projects** with KOLs (e.g. while supporting investigators-initiated studies or company-sponsored clinical trials)
- Ability to **train / teach** and / or develop support documents for companies' collaborators and / or HCPs
- **Capture** and **share insight** gathered through interactions between KOLs' and all customer-facing teams
- **Cooperate** and **coordinate activities** with other **customer-facing collaborators** and **corporate teams** interacting with KOLs
- **Comply with national regulations** and ethical considerations regarding disseminated information (e.g. off-label)
- Ability to **manage time, set priorities** and **adjust unforeseen changes** inherent to MSLs' job

### Expected outputs

- Ability to **inform, challenge** and / or **convince KOLs** based on robust and updated scientific evidence
- **Convince** KOLs to **carry out research** or **clinical studies**
- **Convince** KOLs to **support** the company's **products**
- **Identification** of clinical **research opportunities** with KOLs
- **Effective implementation** of **clinical research** trials
- **Improvement** of participants **knowledge, understanding** of the **disease area** and of the **benefits** of the company's **products**
- **Profiling** and **selecting** the relevant **KOLs to partner with**
- **Fulfilling** of **KOLs needs** related to MSL activities
- MSLs being the preferential contact of KOLs, they will **ensure consistent interactions** and **address potential issues**
- **Prevent the company** to **be sued** and to **be fined**
- **Timely and proper execution** of multiple tasks under the responsibility of MSLs

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

## 2. MSLs' performance management

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

### Integrated Regional Strategic Plan – Principle



Sources: Smart Pharma Consulting

<sup>1</sup> In compliance with the national regulation and the companies' policies – <sup>2</sup> Patient Advocacy groups

## 2. MSLs' performance management

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

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



#### Structure

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

## 2. MSLs' performance management

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

### Integrated Regional Strategic Plan – Specific tools of the Medical Section (1/6)

#### MSL Advanced SWOT

<b>Opportunities</b>	Relative importance <sup>1</sup>	<b>Threats</b>	Relative importance <sup>1</sup>
<p><b>What regional changes are likely to favor the medical environment?</b></p> <p><i>National &amp; regional regulations: relating to MSLs' activities (e.g. off-label communication, invitation process to congresses, grants, etc.)</i></p> <p><i>KOLs' opinion &amp; position: re. the company and its products, KOL's level of influence</i></p> <p><i>Scientific events: regional congresses, other meetings</i></p>		<p><b>What regional changes are likely to disfavor the medical environment?</b></p> <p><i>National &amp; regional regulations: relating to MSLs' activities (e.g. off-label communication, invitation process to congresses, grants, etc.)</i></p> <p><i>KOLs' opinion &amp; position: re. the company and its products, KOL's level of influence</i></p> <p><i>Scientific events: regional congresses, other meetings</i></p>	
<b>Strengths</b>	Relative importance <sup>1</sup>	<b>Weaknesses</b>	Relative importance <sup>1</sup>
<p><b>What are the absolute or relative advantages of the company's medical activity at regional level vs. competition?</b></p> <ol style="list-style-type: none"> <li><b>1 Relationships with KOLs:</b> quality and sustainability</li> <li><b>2 Scientific communications:</b> congresses, staff meetings, symposia, etc.</li> <li><b>3 Support to trials:</b> company-sponsored trials and IIS<sup>2</sup></li> <li><b>4 Training:</b> of speakers, med. reps, new MSLs, etc.</li> <li><b>5 Competitive intelligence:</b> data gathering and analysis</li> </ol>		<p><b>What are the absolute or relative disadvantages of the company's medical activity at regional level vs competition?</b></p> <ol style="list-style-type: none"> <li><b>1 Relationships with KOLs:</b> quality and sustainability</li> <li><b>2 Scientific communications:</b> congresses, staff meetings, symposia, etc.</li> <li><b>3 Support to trials:</b> company-sponsored trials and IIS<sup>2</sup></li> <li><b>4 Training:</b> of speakers, med. reps, new MSLs, etc.</li> <li><b>5 Competitive intelligence:</b> data gathering and analysis</li> </ol>	

Sources: Smart Pharma Consulting

<sup>1</sup> Ranking from 5 = very important to 1 = limited importance

## 2. MSLs' performance management

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

### Integrated Regional Strategic Plan – Specific tools of the Medical Section (2/6)

#### MSL Strategy Card



## 2. MSLs' performance management

The “KOL Partnership Plan” is part of the Integrated Regional Strategic Plan and specifies the objectives of the partnership, its scope and duration

### Integrated Regional Strategic Plan – Specific tools of the Medical Section (3/6)

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

KOL name	(First name – surname)	Medical status	MD – head of medical department – professor of medicine, etc.	Medical setting	Private clinic – private hospital – public hospital – teaching hospital
Interest/ Expertise	(e.g. Pulmonology, cardiology, etc.)	Reputation/ Influence	Private hospital – public hospital – teaching hospital – private office	Advocacy potential	Address & City
Role	(Describe briefly his role vis-à-vis the KOL)		Coordination with...	(Indicate the other collaborators with whom to coordinate)	
Objectives of the partnership	▪				
Specific scope of the partnership <sup>1</sup>	▪	▪	▪	▪	▪
Duration of the partnership	Starting date			Ending date	
	▪		▪		

Sources: KOL Partnership Model 2016 by Smart Pharma Consulting

<sup>1</sup> Examples: Development of a digital tool to improve patients adherence, Coordination of a multi-centric study, Expert support to estimate the medico-economic value of a new product, Lectures during medical meetings organized with peers, etc.

## 2. MSLs' performance management

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

### Integrated Regional Strategic Plan – Specific tools of the Medical Section (4/6)

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

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

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

Sources: KOL Partnership Model 2016 by Smart Pharma Consulting

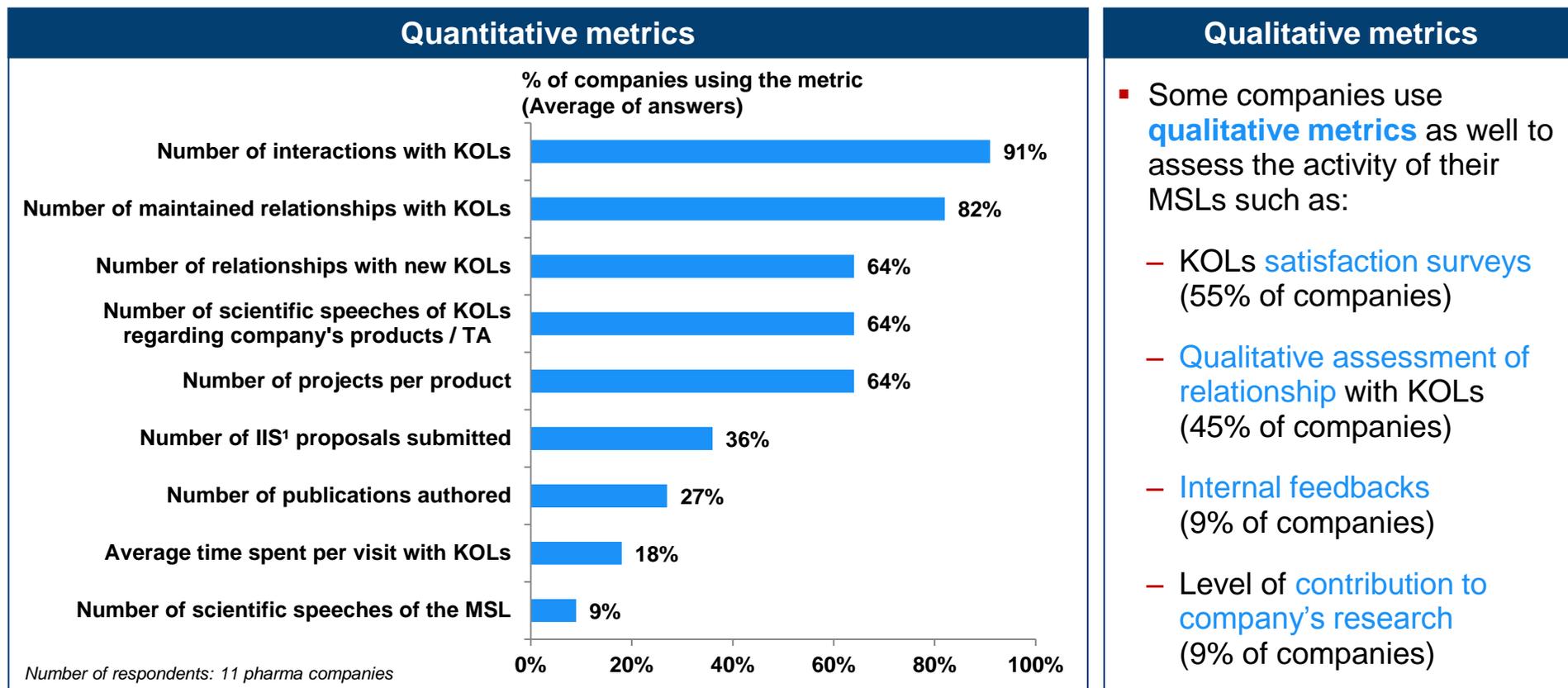
<sup>1</sup> This card should be duplicated by service / activity

## 2. MSLs' performance management

The assessment of MSLs' activity often includes quantitative criteria based on their relationships with KOLs since they are not allowed to be incentivized on sales

### Integrated Regional Strategic Plan – Specific tools of the Medical Section (5/6)

#### Performance metrics to assess MSLs' activity – Current practice in Europe



Sources: "Aligning the Activities and Goals of Medical Science Liaison Teams for Strengthened Corporate Sustainability", MSL World – Smart Pharma Consulting analysis

<sup>1</sup> Investigator Initiated Studies

## 2. MSLs' performance management

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

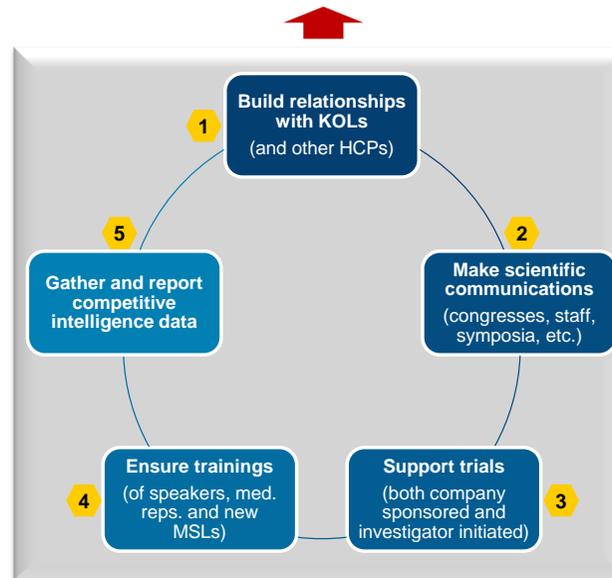
### Integrated Regional Strategic Plan – Specific tools of the Medical Section (6/6)

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

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

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

- Number of people trained
- Qualitative feedbacks of trained people



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

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

### 8 Recommendations *to Boost MSLS' Performance*

1. Clarify MSLS' **roles** and **responsibilities** to HCPs and collaborators of the company to avoid **confusion** with medical representatives' roles
2. Focus MSLS' activities on **KOL recruitment** and **KOL partnership management**<sup>1</sup>
3. Maintain a **high scientific** level of **knowledge** and of **understanding** to guarantee **highly valued interactions** and **strong relationships between** the **MSLS** and the **KOLs**
4. Make sure that MSLS' **activities** are **consistent** with their **ambition** and their **strategic priorities**, defined both at national and regional levels
5. Develop an **Integrated Regional Strategic Plan**<sup>2</sup> including a **Medical section** formalizing MSLS' **ambition, strategic priorities** and key **activities, in accordance** with marketing, sales, market access and compliance departments' priorities
6. Define **quantitative** and **qualitative metrics** to **monitor** MSLS' **activities** and **identify** potential **corrective measures** to be introduced to **improve** MSLS' **efficacy** and **efficiency**
7. Make the **best use** of **MSLS' limited time** by prioritizing their efforts and promoting the use of new communication technologies
8. Define **internal guidelines** and a **control process** to prevent any **compliance issues** that could damage the corporate reputation

## Core capabilities

### 1 Strategy

- Assessing the attractiveness of markets (Hospital / retail innovative products - Vaccines - OTC - Generics)
- Growth strategy
  - Optimization of marketing / sales investments
  - Development of a company in the hospital market Business
  - Valuation for acquisition
  - Portfolio / franchise assessment
- Extension of product life cycle performance
  - Improvement mature products performance
  - Adaptation of price strategy
- Defense strategies vs. new entrants
- Competitive strategies in the hospital market
- Strategic partnerships companies / pharmacies

### 2 Management

- Facilitation and structuring of strategic thinking for multidisciplinary product teams
  - Key challenges identification
  - Strategic options formalization
  - Resource allocation optimization program
- Training of marketing and market research teams to sales forecast techniques (modeling and scenarios development)
- Development and implementation of a "coaching program" for area managers
  - Sales reps coaching
  - Regional action plans roll-out
- Development and implementation of a "sales techniques program" for sales forces (STAR<sup>1</sup>)

<sup>1</sup> Sales Techniques Application for Results (training course)



### 3 Organization

- Rethink of operational units organization
- Improvement of sales force effectiveness
- Improvement of the distribution channels covering the hospital and retail markets
- Development of a strategic planning process