



Medical Science Liaisons

- A New Strategic Lever -

Recommendations to Boost MSLS' Performance

February 2016

Introduction

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

Context & Objective

- **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 MSLs¹
 - Proposes a process, tools and...
 - Makes strategic recommendations...

... to boost MSLs' performance

1. MSLs' current role & responsibilities

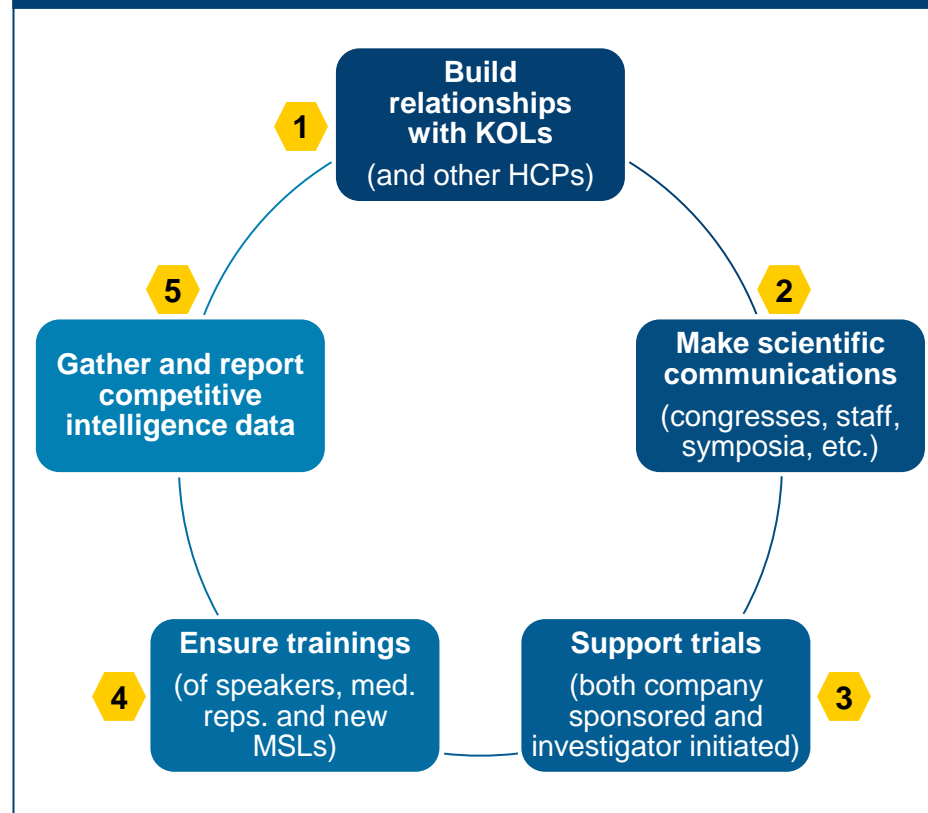
MSLs are the field team of medical affairs in pharma companies, who are dedicated to the development of relationships with KOLs and to high-level scientific communications

Overview

MSLs: Medical Science Liaisons¹

- 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 activities² 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

¹ 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 – ² Excluding administrative time

1. MSLs' current role & responsibilities

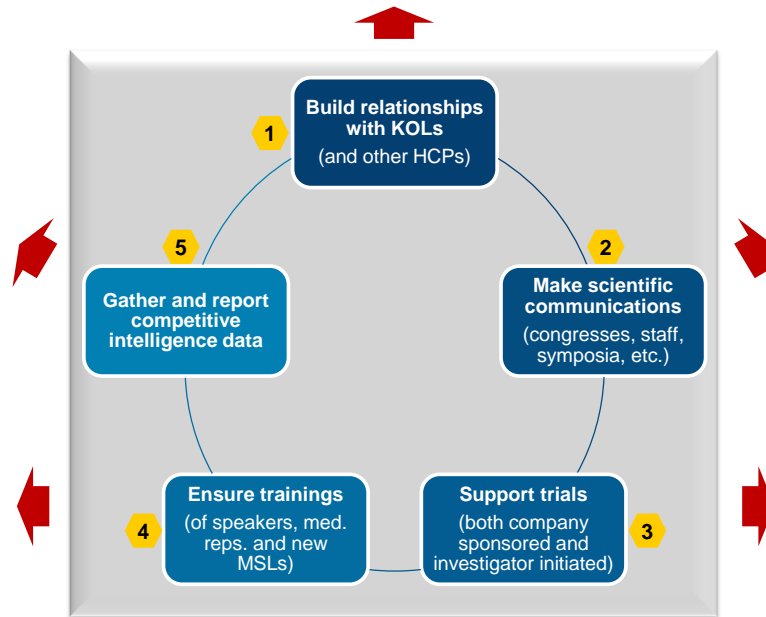
MSLs are often asked to cover a large scope of activities in collaboration with both internal and external stakeholders

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)¹: 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&O²



- 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

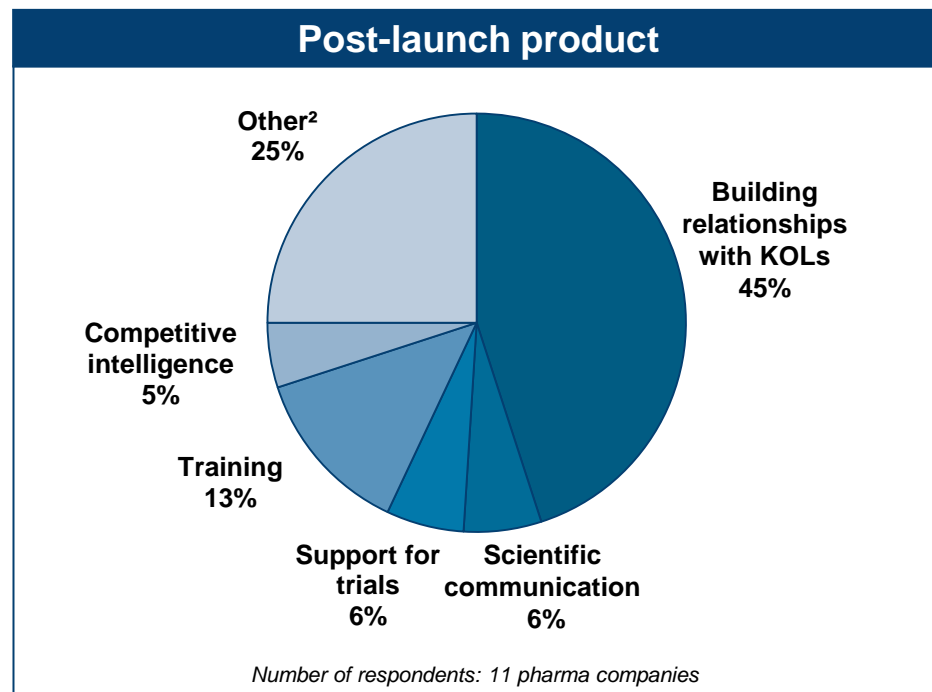
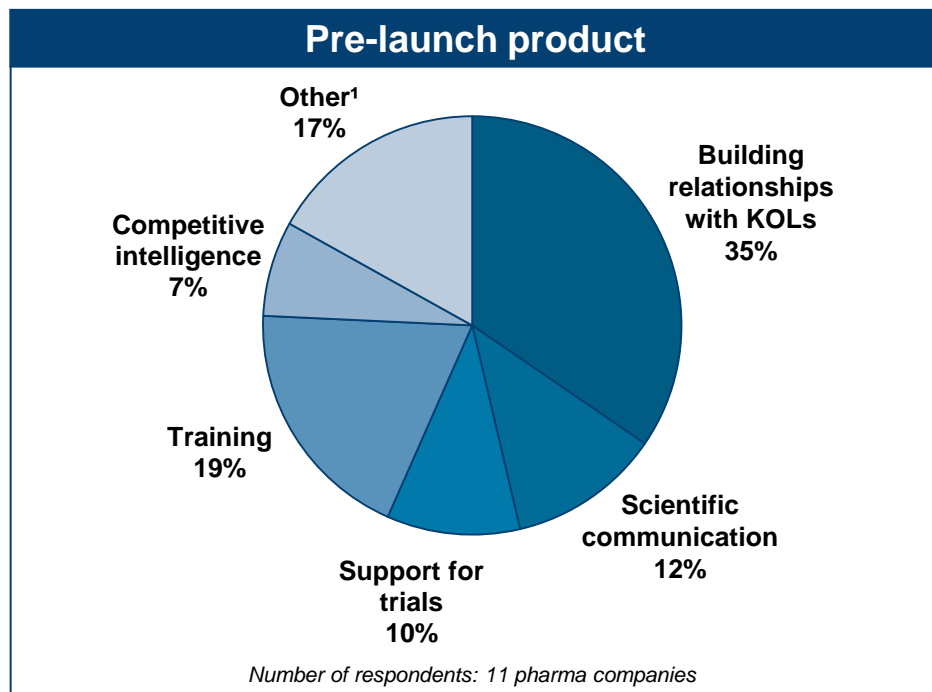
¹ Also called: Investigator-Initiated Trials or IIT – ² Frequently Asked Questions & Objections

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



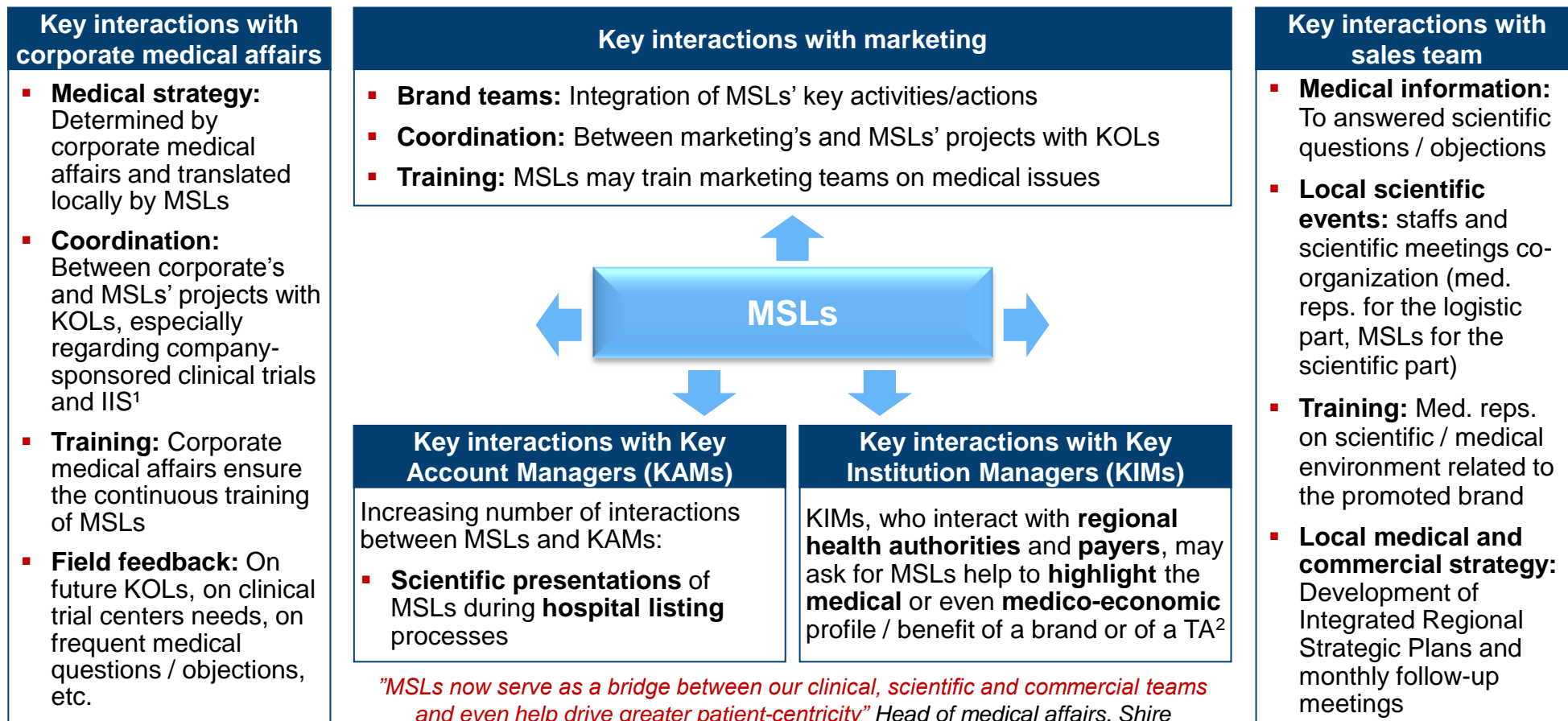
Sources: "Aligning the Activities and Goals of Medical Science Liaison Teams for Strengthened Corporate Sustainability", MSL World – Interviews with 5 MSLs – Smart Pharma Consulting analysis

¹ Including pre-launch transversal activities with marketing or medical teams, etc. –
² 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

¹ Investigator Initiated Studies – ² 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 Programs¹ 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 SOPs² that clarify the Do's and Don'ts in terms of compliance for employees, including for MSLs

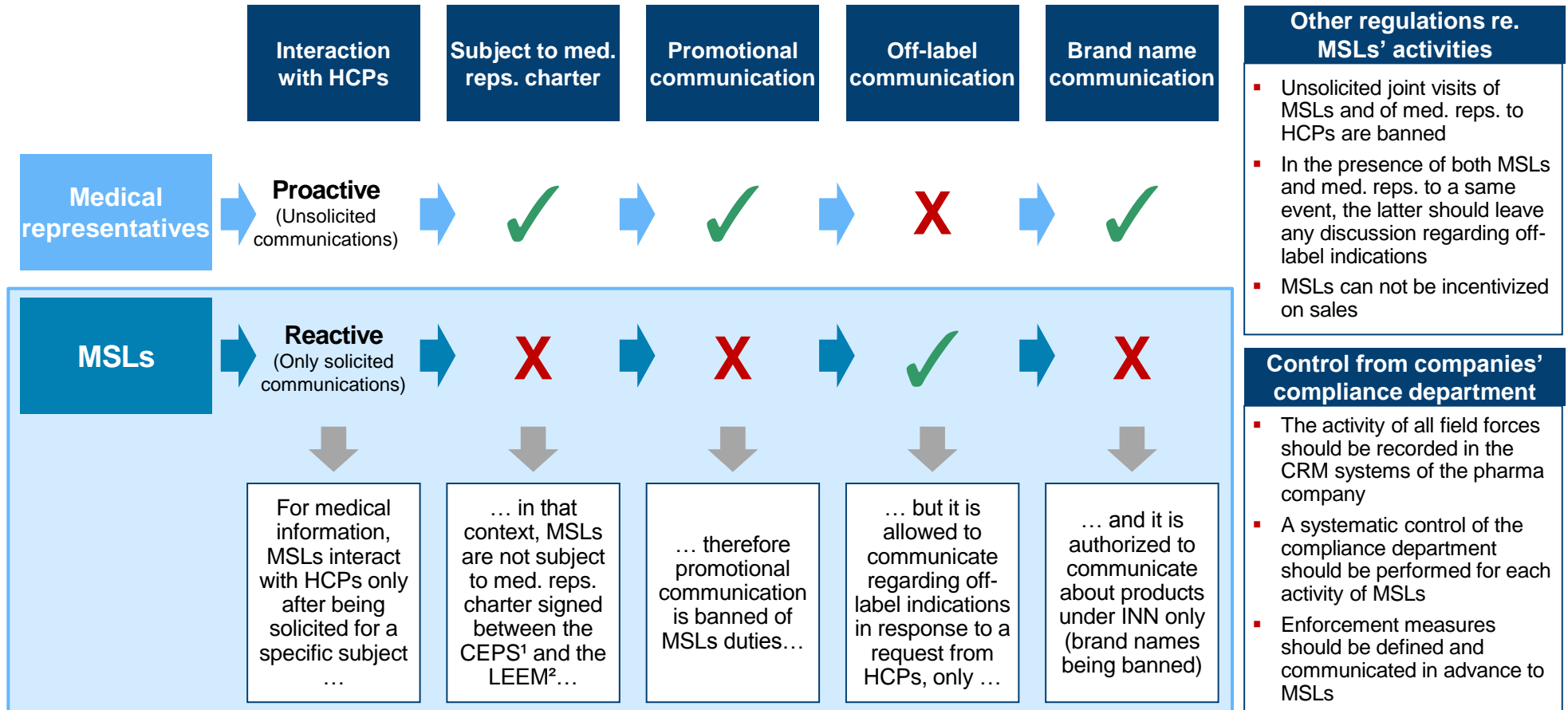
Sources: "MSL-KOL Engagement", FirstWord Dossier June 2011 – MSL Institute – Smart Pharma Consulting analysis

¹ Two types: Compassionate Use Programs (CUPs) or Named-Patient Programs (NPPs) – ² 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

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

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' activities¹

Integrated Regional Strategic Plan – Principle



Sources: Smart Pharma Consulting

¹ In compliance with the national regulation and the companies' policies – ² 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 IIS¹ 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 analysis²
- **Ambition & strategic priorities**
 - Ambition setting
 - Strategic priorities to fulfil the ambition (MSL Strategy Card)²
 - 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

| Opportunities | Relative importance ¹ | Threats | Relative importance ¹ |
|---|----------------------------------|---|----------------------------------|
| <p>What regional changes are likely to favor the medical environment?</p> <p><i>National & regional regulations: relating to MSLs' activities (e.g. off-label communication, invitation process to congresses, grants, etc.)</i></p> <p><i>KOLs' opinion & 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>What regional changes are likely to disfavor the medical environment?</p> <p><i>National & regional regulations: relating to MSLs' activities (e.g. off-label communication, invitation process to congresses, grants, etc.)</i></p> <p><i>KOLs' opinion & position: re. the company and its products, KOL's level of influence</i></p> <p><i>Scientific events: regional congresses, other meetings</i></p> | |
| Strengths | Relative importance ¹ | Weaknesses | Relative importance ¹ |
| <p>What are the absolute or relative advantages of the company's medical activity at regional level vs. competition?</p> <ol style="list-style-type: none"> 1 Relationships with KOLs: quality and sustainability 2 Scientific communications: congresses, staff meetings, symposia, etc. 3 Support to trials: company-sponsored trials and IIS² 4 Training: of speakers, med. reps, new MSLs, etc. 5 Competitive intelligence: data gathering and analysis | | <p>What are the absolute or relative disadvantages of the company's medical activity at regional level vs competition?</p> <ol style="list-style-type: none"> 1 Relationships with KOLs: quality and sustainability 2 Scientific communications: congresses, staff meetings, symposia, etc. 3 Support to trials: company-sponsored trials and IIS² 4 Training: of speakers, med. reps, new MSLs, etc. 5 Competitive intelligence: data gathering and analysis | |

Sources: Smart Pharma Consulting

¹ 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 ¹ | ▪ | ▪ | ▪ | ▪ | ▪ |
| Duration of the partnership | Starting date | | | Ending date | |
| | ▪ | | ▪ | | |

Sources: KOL Partnership Model 2016 by Smart Pharma Consulting

¹ 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 Card¹

| 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

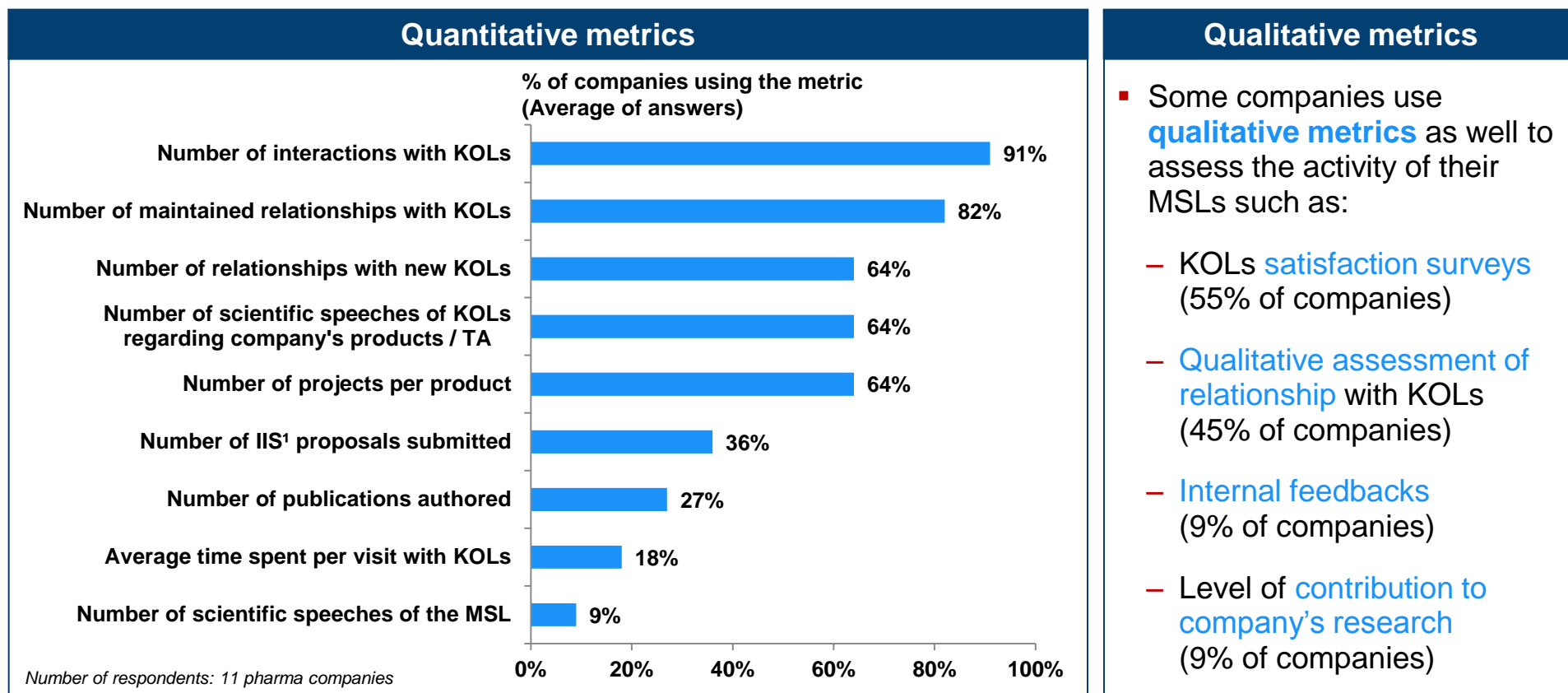
¹ This card should be duplicated by service / activity

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

¹ 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

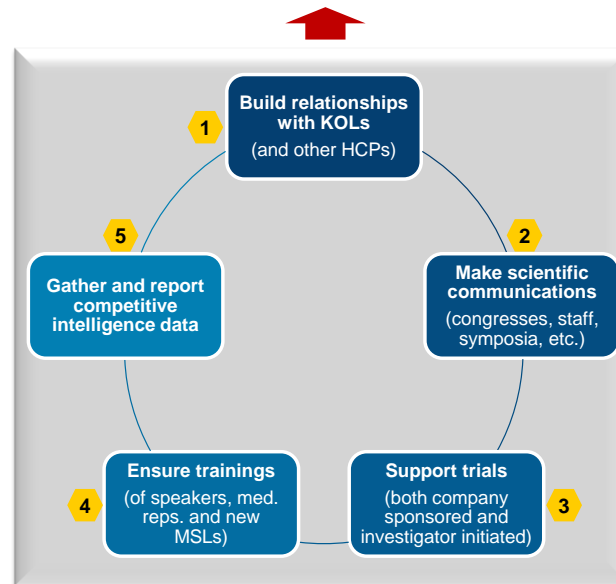
Integrated Regional Strategic Plan – Specific tools of the Medical Section (6/6)

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 IIS¹ 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**¹
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**² 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 (STAR¹)

¹ 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