MEDICAL AFFAIRS

COMPLIANCE

ANALYZE THE INVOLVEMENT OF MEDICAL AFFAIRS IN COMMERCIAL ACTIVITIES

APRIL 27, 2017
AGENDA

Introductions

Strategic Planning and the Interface between Medical Affairs and Commercial

Case Study

Polling Questions and Group Discussion
INTRODUCTIONS
MODERATORS

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STRATEGIC PLANNING AND THE INTERFACE BETWEEN MEDICAL AFFAIRS AND COMMERCIAL
OVERVIEW OF COMPLIANCE FRAMEWORK

+ No statutory or regulatory requirement to have a Medical Affairs department or function

+ As a general matter, the same laws and regulations apply to Medical Affairs personnel that apply to Sales and Marketing personnel. This includes, but is not limited to:
  - The Food, Drug, and Cosmetic Act
  - The Anti-Kickback Statute

+ A primary purpose of Medical Affairs should be to help ensure that non-promotional interactions remain appropriately non-promotional and are not tainted by Sales and Marketing considerations or influence
  - Company organizational structure, processes, and incentives also should be designed and administered to avoid inappropriate influence or the appearance of inappropriate influence
PROMOTION VS. SCIENTIFIC EXCHANGE

Promotion
+ Generally, would include express or implied written or oral statements distributed to or made to customers and/or patients by a company or its representatives with the intent to proactively communicate attributes (e.g., safety, effectiveness, indication, etc.) of company-promoted products and their use
+ Examples:
  - Sales aids, brochures, notes, email messages, blog postings, social media, website materials, videos, etc.
  - Proactive statements made during in-person, phone, or email discussions with HCPs

Scientific Exchange
+ Typically understood to refer to the dissemination and discussion of scientific research/medical findings, without making promotional claims about a product
+ Examples of practices commonly understood to be scientific exchange:
  - Responding to unsolicited requests for off-label information in accordance with FDA draft guidance
  - Distributing scientific and medical publications on off-label uses in accordance with FDA draft guidance
  - Providing financial support for independent medical education programs
  - Appropriate scientific discussions at legitimate scientific or medical conferences
  - Scientific advisory meetings/focus groups, in appropriate circumstances and with limitations
  - Appropriate communications intended for recruitment of clinical investigators and study subjects
DEFINING MEDICAL AFFAIRS AND KEY FUNCTIONS

- **Medical Affairs**: Refers to all the functions dedicated to building and maintaining relationships with physicians and the medical community, including, but not limited to, the following:
  - **Medical Education**: Responsible for CME & educational grants.
  - **Medical Communications & Publications**: Develops or reviews scientific/medical content—including medical journal articles—for communications to healthcare professionals, patients, consumers, and payers. Develops/ manages publication plan. Includes Medical Info Call Center.
  - **Medical/Clinical Research Operations**: Creates and guides strategy for clinical development programs. Develops and executes investigator and company-initiated clinical studies, including cost-marketing/Phase IV studies. Includes Medical Directors.
  - **Medical/Scientific Liaisons (MSLs)**: Non-sales field force responsible for medical relations & training.
  - **Outcomes Research**: Collects and analyzes Health Outcomes/Economics data.
  - **Pharmacovigilance/Safety**: Oversees the collection and analysis of information on adverse drug reactions.
  - **Thought Leader Management**: Responsible for the identification, recruitment and development of physicians who can influence the medical perspective and practice of their peers.
Early Commercial
- Disease analysis and indication sequencing
- Initial commercial opportunity assessment and revenue target
- Product concept/TPP testing
- Initial access environment assessment

Pre/Post Launch
- Long range forecast
- Market positioning strategy and messaging
- Access planning (payer needs, by country)
- HEOR requirements
- Field resourcing (sales, clinical, scientific support)

LCM
- Competitive monitoring and response
- Marketing strategy evolution
- New indications, formulations, publications
- Franchise/portfolio planning

Medical Affairs Functions (Examples)

<table>
<thead>
<tr>
<th>Clinical Context/Expertise</th>
<th>Medical Education</th>
<th>Scientific Communications</th>
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<tbody>
<tr>
<td>Investigator Management/IIS</td>
<td>MSL Management</td>
<td>Surveillance</td>
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<tr>
<td>KOL Engagement and Relations</td>
<td>Publications</td>
<td>Trial Design and Demonstration</td>
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MARKET TRENDS – MEDICAL AFFAIRS IMPERATIVES

Key Life Sciences Trends

+ More aggressive and sophisticated access management
+ Outcomes metrics being used more broadly (indications, payers)
+ Provider integration and IT investment as enabler of HECON--and new payer audience
+ Emergence of new decision-makers (e.g. hospital admin, hospitalists, patients/ advocacy, etc.)
+ Increasingly patient centric (and longitudinal) approach to care delivery
+ Increasing biopharma and medtech reliance on emerging markets

Medical Affairs Imperatives

+ Address shift in definition of value and associated information requirements
+ Engage new stakeholders and tailor content of communication accordingly
+ Embrace “patient journey” approach
+ Understand and harness new, digital media channels where appropriate
+ Build expertise and structure organization in a way that addresses needs (region specific)

...execute in an increasingly rigorous and transparent regulatory environment
WHAT IS APPROPRIATE FIREWALL BETWEEN MEDICAL AFFAIRS AND COMMERCIAL?

The changing healthcare environment has encouraged the formation of independent Medical Affairs departments.

There is not a rigid set of requirements that dictate how a Medical Affairs department should look or operate.

As a result, the industry has developed a wide variety of models, all seeking to address intensified public and regulatory scrutiny.

Typical models:

1. Prohibit all communication between medical affairs and commercial.
2. Allow open communication between medical affairs and commercial.
3. Establish guardrails and protocols to allow compliant communication between medical affairs and commercial.
CASE STUDY
WHAT IS AHUS?

aHUS is an ultra-rare disorder caused by a genetic change to the proteins, which regulate the Complement System.

DIAGNOSING AHUS CAN BE COMPLEX

Thrombocytopenia + Microangiopathic Hemolysis

Plus symptoms in at least one of these organ systems:
- Neurologic
- Renal
- Gastrointestinal
- Cardiovascular
- Pulmonary
- Visual

ADAMTS 13 and Shiga Toxin Laboratory Tests

- ADAMTS 13 ≤ 5%
  - TTP
- ADAMTS 13 > 5%
  - aHUS
- Shiga Toxin positive
  - Shiga Toxin positive E. coli HUS

aHUS is an ultra-rare disease, with an estimated 2 cases per million Americans.
ISSUES

• Sales team would hit a wall with Japanese physicians when educating on disease.

• Rarity of disease and lack of treatment experience led to physicians not fully grasping urgency to treat, potential complications in diagnosis, etc.

• Higher level scientific discussions with physician led by Medical Affairs was seen as necessary to assist in critical patient cases.

• Hand-off from Sales to Medical Affairs was formal and standard engagement process took days.
  
  • Followed standard Medical Information Request Process
  
  • This process timing didn’t meet patient need in critical cases
ISSUES

• Medical felt that many activities they were being asked to do were “promotional”
  • What was their definition?

• What are MSLs “allowed” to do if there is a gap in HCP understanding or a misunderstanding?

• What if an HCP isn’t abiding by the label or treatment guidelines then what can an MSL do?

• Do we need to get a Medical Info Request form every time? In critical cases? What about when we have one?
CONSIDERATIONS

• What are the legal boundaries related to Medical/Commercial interactions? Any cases on point? Industry norms?

• What is our company philosophy on the issue? What do we want to achieve and how do we want to achieve it? What do we want the roles & responsibilities to be?

• What is common practice in Japan on these kinds of activities?

• Based on the above, what will our personnel be comfortable with? Even if we can do something, should we do it that way and will our people follow through?

• In rare disease, should we make exceptions or change our behavior from industry norms? What about in critical patient cases?
LEGAL/COMPLIANCE GUIDELINES

- Japan and global leadership working to solidify SOPs related to commercial and medical interactions with HCPs in Japan

- Guidance obtained from both internal medical/compliance/legal leadership as well as outside counsel

- There is no rule in Japan which deems a proactive communication by an MSL to an HCP to be promotional

- There is nothing that prevents proactive communication with HCPs by medical staff

- There are no specific requirements in terms of process or timing for communications with HCPs by medical
WAYS OF WORKING

Ensure we Start with Common Purpose

The High Performance Team

- Clear Roles & Responsibilities
- Effective Leadership
- Efficient Processes
- Mutual Understanding
- Effective Communication
- Common Purpose

Continue to Improve Communication
Agree on Realistic Expectations
Better Define Roles & Responsibilities

Ensure we Start with Common Purpose
# COMMERCIAL AND MEDICAL RACI

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<tr>
<th>Event</th>
<th>Responsible</th>
<th>Accountable</th>
<th>Consulted</th>
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<tbody>
<tr>
<td>aHUS forum</td>
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<td>aHUS masters meeting</td>
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<td>aHUS CET</td>
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<td>Symposia/Company Sponsored Seminar</td>
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<td>Regional seminar</td>
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<td>Explanatory meeting</td>
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<td>Medical Education Seminar/Symposia in scientific session of congress</td>
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<td>Medical Roundtable Meeting</td>
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<td>Advisory Board Meeting</td>
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<td>Preparing publications</td>
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<td>Addressing requests from physicians – UMR *</td>
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<td>Addressing inquiries from physicians – investigator sponsored research</td>
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<tr>
<td>Distributing and discussing latest publications/ scientific data (on label)</td>
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<tr>
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<tr>
<td>Critical complicated patient cases (actions included Clinical case conference in Regional Sales Meetings)</td>
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*To follow UMR response flow, MCC responds on-label UMR. MSL responds off-label and highly scientific case, and UMR from medical KOL.
MARKETING “ACCOUNTABLE” TASKS

aHUS forum & Symposia/company sponsored seminar

- Draft contents, agenda and key message
- Negotiate contents/presentation with speakers
- Confirm speaker slide to be aligned to requested content

aHUS masters meeting & CET (from 2017)

- Draft contents, agenda and key message
- Negotiate contents/presentation with speakers
- Confirm speaker slide to be aligned to requested content

* SE with medical KOL as speaker and with the other speaker if requested by speaker
MARKETING “ACCOUNTABLE” TASKS

Regional Seminar
- Draft contents, agenda and key message
- Negotiate contents/presentation with speakers
- Confirm speaker slide to be aligned to requested content

Explanatory Meeting
- Share key message and content
- MCC educational program under MCC educational plan

1. Recommends candidate speaker & chairman
2. Advice on Content
3. SE with speakers**
4. Compliance review
5. Participates for compliance and content review at seminar

*On label responded by MCC, Off label responded by MSL
**SE with medical KOL as speaker and with the other speaker if requested by speaker
MEDICAL “ACCOUNTABLE” TASKS

**Med. Ed Seminar/ Symposia**

1. Negotiate with chair of congress
2. Select speaker and chairman
3. Draft presentation story and discussion with speakers through SE

**Med. Roundtable**

1. ML/ MS selects attendees, drafts content and holds meeting with MSL
2. MSL contacts attendees for contracts, and exchange scientific opinion
3. Hold as closed meeting chaired by Alexion Medical Director
4. Post meeting contacts, scientific exchange and collect insight
5. ML updates Medical Plan with collected insight

**Ad. Board**

1. ML/ MS selects advisors, drafts content and holds meeting with MSL
2. MSL contacts advisors for contracts, and exchange scientific opinion
3. Hold as closed meeting chaired by Alexion Medical Director
4. Post meeting contacts, scientific exchange and collect insight and advise
5. ML updates Medical Plan with collected insight and advise

*The program is a part of congress scientific session, which is reviewed by the congress program committee*
POLLING QUESTIONS
POLLING QUESTIONS

- Does the current Strategy for your Commercial activity align with the Medical Affairs Department?
  - Yes or
  - No

- Does Medical Affairs provide input into Commercial strategic planning?
  - Yes or
  - No

- Does Compliance have a role in the strategic planning process?
  - Yes or
  - No

- If Commercial and Medical align on strategic planning, does it cover specific issues such as: check all that apply
  - Publications Planning
  - Medical Information Responses
  - Advisory Boards
  - Grant Requests
Thank you

Please contact us if you have any additional questions or would like to reach out to us regarding this presentation.

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