MEDICAL SCIENCE LIAISON GUIDELINES

2018
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Overview

Preamble and Disclaimer

The Medical Science Liaison Society (MSL Society) is a 501c3 nonprofit organization and is exclusively dedicated to advancing the global MSL profession. The MSL Society serves as a voice for the profession by building further awareness of the important contributions that MSLs make in advancing science that improves the quality of life for patients. The MSL Society has prepared these guidelines as a useful tool to ensure that the profession continues to be an effective leader in making important contributions to the companies that employ MSLs.

The information provided in this document is designed to provide guidelines for the activities of field-based Medical Science Liaisons (MSLs) and it contains information generally applicable globally. Companies should consider these guidelines when developing their own policies and standards for their MSLs. However, these guidelines are just that—guidelines. One size does not fit all. *These guidelines are intended to provide guidance for the global MSL profession and the companies that employ them, but they should not be viewed as a code or rules or laws; this document does not supersede local laws and regulations, regional codes, or individual company codes of conduct.*

All activities must comply, as appropriate for local use, with applicable policies, including but not limited to those defined in AdvaMed, PhRMA, ABPI, EFPIA, FDA, OIG, INTERFARMA, ANVISA, and all other relevant regulations governing such activities in the region(s) in which the activities are being performed. Although this is intended to be a global guideline document, not all regulations will apply to every country’s laws. As a result, MSLs should be periodically assessed to ensure that they comply with relevant company policies and standards of conduct per Section 14 of the PhRMA Code on Interactions with Healthcare Professionals.

There are a variety of valid reasons why a guideline may not make sense or may be unduly restrictive. For example, any of the following circumstances would require a company and its MSLs to have policies or standards that may differ from these guidelines:

- Resource restrictions, particularly for small companies.
- The stage of the technology.
- The type of condition that is being treated.
- The unique risks, benefits, and indications of the drug or device.

Provided that the company employing the MSL and the MSLs themselves develop reasonable policies and standards that are appropriate and meet the underlying spirit of these guidelines, such activity should not be considered in and of itself a violation of these guidelines.
Purpose of This Document

This document presents current and appropriate comprehensive guidelines and recommendations related to the activities of Medical Science Liaisons (or equivalent title).

The primary goal of these guidelines is to serve as a reference for appropriate internal and external activities for Medical Affairs Leadership, MSL management, as well as new and experienced MSLs. These guidelines apply to all field-based MSLs or other equivalent roles. Many companies use various alternatives to the Medical Science Liaison title, even though the roles have similar or equivalent responsibilities. Some alternate and equivalent titles include but are not limited to:

- Clinical Liaison
- Clinical Science Consultant
- Clinical Science Liaison
- Clinical Science Specialist
- Clinical Specialist
- Clinical Trial Educator
- Clinical Trial Liaison
- Field Medical Director
- Global Medical Advisor
- Market Access Liaison
- Medical Advisor
- Medical Development Advisor
- Medical Liaison
- Medical Liaison Manager
- Medical Manager
- Medical Outcomes Liaison
- Medical Relationship Manager
- Medical Science Consultant
- Medical Science Manager
- Medical Scientific Director
- Medical Scientist
- Molecular Science Liaison
- Precision Medicine Liaison
- Regional Medical Advisor
- Regional Medical Director
- Regional Medical Liaison
- Regional Medical Manager
- Regional Medical Scientist
- Regional Scientific Manager
- Remote Medical Liaison
- Scientific Affairs Manager

This document sets forth the guidelines that govern the operations and activities of MSLs. It defines the typical activities and responsibilities of MSLs and establishes standards to ensure that MSL activities are primarily focused on: (1) fostering ethical relationships with key opinion leaders (KOLs) also referred to as external experts (EEs), thought leaders (TLs), medical experts (MEs), key thought leaders (KTLs), or opinion leader (OLs); and (2) facilitating the exchange of valid, unbiased, fair, and balanced scientific information within the context of a medical product or device and the therapeutic area that the MSL supports. It also establishes standards to ensure that MSL-related activities and materials are educational in nature, are unbiased and scientifically valid, and do not represent (implicitly or explicitly) off-label promotion or advertising of any product that is subject to the requirements of the Federal Food, Drug, and Cosmetic Act; applicable FDA regulations; EMA/EFPIA regulations and guidance, as applicable to the MSL’s location; or any other local regulation in a geographical location where the MSL activity is being performed.

MSL Role Defined

A Medical Science Liaison is a specific role that typically reports into the medical affairs department within a pharmaceutical, biotechnology, medical device, medical diagnostic, contract research organization, or other healthcare company. MSLs typically have advanced scientific training and academic credentials typically consisting of but not limited to a doctorate degree (PhD, PharmD, MD, etc.) in the life sciences and concentrate on a specific therapeutic area (e.g. oncology, cardiology, CNS, pulmonary, hematology, surgery, women’s healthcare, etc.), product, diagnostic, or disease state. MSLs may have BPharm, MPPharm, MS, MSc, DNP, DNS, RD, PA, or alternate advanced degrees as well as clinical expertise in relevant therapeutic areas.
MSLs serve as scientific peers and resources within the medical community and health systems. MSLs are also scientific experts to internal colleagues at companies. However, the primary purpose of the MSL role is to foster ethical relationships with leading KOLs in a manner that is professional and with integrity. MSL communication should always reflect fair balance.

MSLs should receive relevant therapeutic, compliance, and MSL core skills training as well as company product and pipeline training prior to engaging in external facing activities. It is considered good practice for companies to have an MSL onboarding period, training plan, and validation or formal assessment process in place that includes appropriate training about relevant country medical laws and regulations, promotional codes, company SOPs, and coverage of healthcare systems and processes. Additionally, MSLs who may work or support clinicians should be given training on appropriate etiquette; if working in clean rooms or operating theatres, MSLs should have received appropriate training. Maintaining MSL training and certified competency documentation is strongly advised.

### Scientific Engagement with KOLs

Scientific engagement is an important function of the MSL. Scientific engagement is the process of responding to medical inquiries and appropriately proactively engaging with KOLs in meaningful scientific exchange. During these engagements, the MSL works to develop an ethical peer-to-peer relationship with KOLs in healthcare, academia, payer, and government organizations to disseminate scientific information, gather insights, and evaluate the expert opinion of KOLs. The MSL is expected to be a trusted scientific point of contact within the company. Consequently, these engagements span the product lifecycle to help the company strategically develop drugs or devices; execute pre-, peri-, and post-launch plans; and commercialize products. MSLs must maintain their scientific integrity by fostering truthful and non-misleading medical and scientific communications that are non-promotional in nature.

### Proactive KOL Planning

MSLs should appropriately contribute to or lead the mapping of KOLs; however, such exercises should not be mistaken for targeting customers for commercial objectives. MSLs should not participate in targeting activities (e.g. examining prescribing rates or patterns of KOLs, assessing or rewarding MSL performance based on prescribing, prioritizing MSL activity in alignment with high prescribers, or seeking to assure KOLs prescribe a product). KOLs should never be targeted based on their potential to prescribe. MSL compensation and bonuses must not be connected with product sales or performance, however either may be aligned with overall corporate performance.

- MSLs may use available internal, public (e.g. Google search, institution website, publication author, faculty at CME program, or presenter at scientific session), and purchased information to identify KOLs in their therapeutic area.

- MSLs may prioritize KOLs for engagement based on the needs of their medical plan (e.g. study development, data releases, publications, or product launch). Prioritization should be based on the scientific objectives of the company and not on their commercial potential.

- MSLs may focus on KOL development planning by creating tailored objectives specific to each KOL.

- MSLs may identify and engage with appropriate KOLs based on their scientific interests and background to support the projects/tactics outlined in the medical plan/strategy. Tactics MSLs employ to achieve business goals should also be internally approved for proactive use.

- MSLs and MSL leaders should monitor and report on progress made toward achieving goals.
Introductory Meetings

MSLs may proactively conduct introductory meetings with KOLs and other healthcare professionals (HCPs) during which the MSL may provide contact information, review areas of expertise and therapeutic responsibility, and assess the KOL’s or HCP’s areas of professional and practice interest (e.g. research or education).

Introductory meetings may be conducted with sales colleagues as long as the nature of the conversation remains focused on the creation of an introduction and does not include off-label scientific exchange or product promotion by a sales colleague. To preserve the separation of scientific exchange and promotional discussions, joint visits of MSLs and field sales personnel (i.e. sales representatives and first-line managers) with HCPs are not allowed except for brief introductions. Always refer to the company SOPs and policies, which supersede this guidance.

Scientific Exchange Meetings

Scientific exchange meetings occur between MSLs and KOLs, HCPs, or health system decision makers (or similar bodies) for the purposes of obtaining insights, engaging in the exchange of information through scientific dialogue, and discussing research. This exchange is also intended to foster education to improve the provision of medical care by KOLs or other HCPs in order to benefit patients.

Patient Interaction

MSLs may interact with patient advocacy groups to gather important insights into patients’ concerns and needs, unless prohibited by local laws or regulations. In Europe, promotion to the public is not allowed; the primary focus on any patient interaction is to provide disease awareness information, and MSLs should refer any specific medical inquiry to the patient’s physician or medical care provider. Patients are increasingly using social media to obtain medical information and this platform is playing a more significant role in highlighting patients’ points of view. As a result:

- MSLs can identify medical influencers and then establish useful and innovative ways in which to interact and partner with them.
- MSLs can present relevant scientific information to patients and patient advocacy groups in a manner which they can easily understand.
- MSLs can engage with patient advocacy groups by employing multiple channels, including social and digital media.
- MSLs should follow their company’s policies on the appropriate use of social media.
Non-Promotional Interaction

MSLs are expected to engage with their stakeholders (both internal and external) in a credible, unbiased manner. Their engagement should adhere to the following guidelines:

- Interactions should be ethical, professional, and compliant with global and local company policies at all times.
- Interactions should be scientific in nature, balanced, and non-promotional.
- Interactions should be focused on factual, scientific, and evidence-based medical information, and consistent with the overall weight of credible medical evidence (i.e. not selective), and they should not contain any conclusory statements or misleading information.
- Communication should never contain any false or misleading information, including a failure to provide key information that by omission is misleading, or by omitting any substantial information.
- Field medical activities should be aligned with the medical plan/strategy of the respective business units to which they belong. Their activities should never be driven by commercial/sales objectives or targets (e.g. specific numbers of prescription goals).
- MSLs may have an initial proactive, exploratory meeting with an HCP to determine medical needs, assess KOL criteria, and consider appropriate alignment. Prior to accepting subsequent meetings with an HCP, the MSL should clarify the scientific need/issue with the HCP or with the company’s colleague who referred the matter to the MSL. Evidence for the request must be available before the meeting takes place (i.e. documented HCP signed request, email, or phone confirmation). This is good practice and will permit the MSL to prepare the appropriate information for the HCP.
- Beyond an introductory meeting, if the MSL cannot identify a legitimate scientific need for any requested on-label or off-label exchange or unlicensed information prior to the meeting with the HCP, the MSL should decline the meeting.

Providing Items of Value

Companies should not provide any item of value that would interfere with the independence of an HCP’s prescribing practices as per Section 13 of the PhRMA Code on Interactions with Healthcare Professionals, EFPIA HCP Code, Innovative Medicines Canada Code of Ethical Practices, AdvaMed, etc.

- MSLs may present information to HCPs during their working day, which may be during meal times. In connection with scientific exchange or presentations, it is appropriate for occasional modest meals to be offered as a business courtesy to the HCPs as well as members of their clinical staff attending presentations in compliance with Section 2 of the PhRMA Code on Interactions with Healthcare Professionals. Spouses of HCPs, even if clinicians, should not be included at meals if their medical specialty is not related to the MSL-led presentation or scientific discussion.
- Reimbursement for meals during MSL-facilitated small group presentations should be from the medical affairs budget and not the commercial (i.e. sales) budget to avoid the appearance of a promotional program.
Recreational activities

- To ensure an appropriate focus on scientific exchange and to avoid the appearance of impropriety, MSLs should not provide any entertainment or recreational items to any HCP as per Section 3 of the PhRMA Code on Interactions with Healthcare Professionals.

- Attendance at non-scientific events is discouraged to avoid any appearance or perception of impropriety.

- MSLs should refer to company policies concerning MSL involvement at events.

Sponsorship

- Continuing medical education (CME) helps HCPs obtain information that can improve patient care; thus, financial support for CME may be provided where in compliance with Section 4 of the PhRMA Code on Interactions with Healthcare Professionals.

- MSLs may discuss the company's medical education grant process upon request from an HCP.

Non-educational items

- Non-educational items (e.g. pens, notepads, mugs, and similar “reminder” items with company or product logos) should not be offered to HCPs or their staff, even if they are accompanied by patient or physician educational materials as per Section 10 of the PhRMA Code on Interactions with Healthcare Professionals.

Proactive Discussion Topics

While many interactions with KOLs or HCPs will be reactive in response to unsolicited requests, there are scenarios in which it is appropriate for MSLs to engage proactively with KOLs or HCPs, including:

- Scientific exchange in a strictly non-promotional manner.

- New on-label data.

- Dissemination of information with regards to any safety concerns or new risk information.

- Introduction to an external stakeholder is allowed in order to explain the MSL role and to establish a consistent point of contact for any scientific exchange.

- Formal medical insight surveys to gain insights from the appropriate audience(s) may be appropriate on issues potentially relevant to a product or therapeutic area (e.g. emerging clinical data, clinical practice trends, or research and development).

- Presentations covering data meant to answer a scientific/medical question that do not suggest or identify a specific product may be appropriate if not yet approved to market in the country location.

- Educational presentations to external stakeholders may be appropriate, including an opportunity to respond to audience questions concerning diseases and their management. Discussion of any individual product may be permitted either as a product class or unique product details such as the mechanism of action in first-to-market where novel science is useful to clinical knowledge. The audience may include groups of HCPs, members of healthcare organizations, and medical scientific associations. These group educational sessions (also known as unbranded scientific education programs) may
be MSL-initiated or MSL-supported to facilitate scientific, disease state discussion; to gain local insights; or to fill identified educational gaps.

- Scientific events including advisory boards, roundtables, or medical education meetings set up by medical affairs aimed to facilitate clinical discussion may be appropriate in order to gather local insights or fill educational gaps on disease state or unmet medical needs. An external stakeholder such as a KOL may be utilized as a co-moderator if such meetings may benefit from a KOL’s perspective in the chosen field.

- Post-medical conference updates may be delivered to an appropriate audience using the company’s medical approved materials via their electronic or paper-based system within the country. This should be provided on a limited basis in a non-promotional manner.

Proactive exchange of information by the MSL related to company products or solutions on an unapproved product or unapproved indication may be allowed in the following circumstances:

- To current investigators performing services under a written contract in ongoing research if such information is relevant to the research and the services being performed and is communicated with the intent to support such investigator services.

- To prospective investigators for proposed research if such information is relevant to the proposed research and services and is communicated with the intent to:
  - Solicit his/her interest in participating in the research; or
  - Support assessment of the qualifications of the investigator and the site for such research upon the company’s request.

- To provide scientific information regarding product safety, risk management plan, etc.

- To communicate with consultants/advisors or potential consultants/advisors as per Section 6 of the PhRMA Code on Interactions with Healthcare Professionals:
  - Only if the disclosure/provision of information is in furtherance of the services being provided and relates specifically and exclusively to the services being provided. A written, executed services agreement must be in place prior to the discussion.
  - For assessing the desirability and viability of retaining their services; such communications should be focused on obtaining information about an HCP’s practices, interests, and research activities but only to the extent necessary to determine if the person or site could perform the service contemplated. A written, executed confidentiality agreement must be in place prior to the discussion.
Documenting Scientific Exchange

MSLs must document all KOL or HCP interactions in the approved customer relationship management (CRM) system or other similar system in line with the company’s policy and data-privacy policies.

- Documentation typically includes customer insights, profiling of interests, and survey data.
- Communication of demographic information and other basic interaction data (e.g. date and time of visit) can be shared post-visit and made visible between medical and commercial CRM tools. However, no data or information on the nature or purpose of the MSL interaction should be visible or available to commercial colleagues.
- Copies of peer-reviewed journal articles may be provided in response to an unsolicited request without promotional and non-promotional approval following the current copyright approval, distribution, and documentation protocols for transparency. Product labeling may be distributed as appropriate along with the article. (Note that the Sunshine Act transfer of value applies in the US. HCPs who request full articles should be informed of Sunshine Act reporting by pharmaceutical companies prior to sending anything to an HCP. Similar statutes such as the UK Bribery Act should be followed in their respective countries.)

Presentation Materials

Data in the form of reprints of published articles, scientific congress posters/abstracts, and written responses to specific questions on the company’s marketed products, solutions, and disease state management may be provided to KOLs or other HCPs in line with local standard operating procedures.

- Such written materials or responses must be pre-approved by the appropriate company’s local procedures framework. All copyright laws will be adhered to when providing such information.
- Slides can only be utilized for their created purpose, which should be communicated within the corresponding briefing document.
- If a KOL or other HCP requests a slide presentation on the company’s product or a particular disease state, it can be provided if such materials have been pre-approved for distribution and use for external stakeholders.
- All written materials that contain off-label or unlicensed information must include a clearly visible indication that the material contains off-label or unlicensed information.

Educational Programs and Group Meetings

In general, when a presentation involves speaking to more than one appropriate HCP, the MSL is required to ensure that the attendees have an appropriate scientific interest and clinical need to attend such meeting, although some companies may have different requirements and/or policies.
Scientific Education Programs

Generally, group education sessions (also known as unbranded scientific educational programs) may be initiated or supported by the MSL to facilitate scientific or disease-state discussions, to gain local insights, or to fill identified educational gaps. Audiences may include groups of HCPs, members of healthcare organizations, and medical scientific associations. These programs may consist of educational presentations, roundtables, journal clubs, etc. The programs may include an opportunity for the audience to ask questions concerning diseases and their management.

Off-label questions that arise in a group setting may be addressed in accordance with local policy and procedures. Education programs are not conducted with commercial colleagues including sales representatives. The program should be non-promotional.

Congress Support

MSLs may attend scientific medical congresses as part of the medical team. At congresses, the MSL must not staff a promotional booth or stand. They should not join members of the commercial team at the company’s promotional booth or conduct scientific conversations with external stakeholders in this area. Responses to medical information inquiries with HCPs should happen at a designated medical information or medical affairs booth or away from the main promotional booth area. Only personnel trained to provide medical information may staff the medical affairs booth.

MSLs may attend relevant scientific sessions and symposia to ensure they maintain a high level of expertise in their respective therapeutic area, keep abreast of the latest medical developments, and interact with KOLs. Approved activities include the following:

Pre-Congress

- Coordinate with colleagues to identify any HCPs that may be attending and arrange meetings with regional/global colleagues if appropriate.
- Attend pre-congress medical team planning session.

During Congress

- Attend relevant scientific sessions, poster sessions, and symposia.
- Attend relevant company meetings.
- Engage in legitimate scientific exchange with KOLs or HCPs where appropriate.
- Attend any regional or global meetings or discussions that have been organized with key stakeholders/HCPs.
- Staff medical affairs booths.

Post-Congress

- Develop and deliver a full meeting report within reasonable timing to the medical affairs team.
- Prepare a meeting report summarizing key points on-license for extended sales and marketing team.
- Prepare post-conference updates to be held with KOLs or HCPs if appropriate, ensuring that such information is permitted to be shared.
- Conduct post-briefing meeting to determine relevance and type of attendance for future meetings.
Responding to Medical Information Requests

MSLs can provide information upon request to any HCP within the approved label indication or off-label information. The request should come to the MSL either directly from the HCP, via the medical affairs department internal process, or via a non-commercial colleague such as R&D. Any scientific exchange of information should be truthful and non-misleading and presented in appropriate context.

Requests for off-label information should be documented as asked to avoid broadening the scope of the question and inclusion of non-requested information. The request for off-label information may be submitted to an MSL directly by an HCP or may be provided by a commercial colleague using an approved medical information request process. The request should be documented along with the HCP’s confirmation in an official company system (i.e. medical information request form).

Note that certain companies may require formal responses to on-label or off-label question and may require use of only pre-approved materials (i.e. medical response document).

Adverse Events

If the engagement reveals an adverse drug event associated with the use of a drug in humans, regardless if it is considered drug-related or not, the MSL is responsible for ensuring that any reportable event is forwarded to the company’s adverse drug reporting process in a timely manner, in line with the company’s pharmacovigilance standard operating procedures, typically within 24 hours.

Joint HCP Visits with Sales Representatives

To preserve the separation of scientific exchange and promotional discussions, joint visits of MSLs and field sales personnel (i.e. sales representatives and first-line managers) with HCPs are not allowed except for brief introductions.

Sales representatives should cease all promotional discussions prior to conducting an introduction and should leave the room prior to any scientific exchange that occurs between an MSL and any HCP. Similarly, MSLs should cease all scientific exchange prior to conducting an introduction and should leave the room prior to any promotional discussion.

In situations where access to an institution or HCP is limited, MSLs and field sales personnel may split an appointment time to allow both medical and commercial agenda topics to be discussed. In these scenarios, MSLs and field sales personnel should essentially have separate meetings with separate agenda topics. As this is a general guidance document, it is advised that MSLs follow company SOPs and policies regarding the ability to use this type of split KOL visit scheme. As an example of split meetings, MSLs may meet with an HCP in a separate room (e.g. HCP’s office) while field sales personnel conduct a promotional discussion with other clinical staff.

MSLs and certain commercial personnel (marketing company presidents, business unit heads, and senior sales/marketing personnel) may engage in joint visits where the discussion remains on-label.

Based on the country-specific situation, MSLs and market access personnel may engage in joint visits with payer customers or hospital decision makers. However, the agenda or sequencing of the meeting should clearly separate the discussion of scientific topics from the discussion of promotional and/or other business topics by commercial colleagues. Refer to local policies, SOPs, and standards for specific guidance.
Evidence Generation

MSLs should play a role in the evidence-generation activities of their organization. Evidence generation includes company sponsored studies, investigator initiated trials (IITs), clinical audits, and HEOR studies. MSLs should receive training on good clinical practice (GCP) and internal company SOPs relevant to clinical trial procedures.

Company Sponsored Studies

MSLs may be asked to support studies sponsored by their organization. The MSL’s role in company-sponsored studies may include:

- Identifying potential study sites based on their scientific capabilities, administrative readiness, and stakeholder interests.
- Proactively informing HCPs about sponsored trials to help recruit investigators (MSLs may have goals about the number of sites with whom they shared information, but may not have specific targets of the number of patients they are responsible for enrolling).
- Providing medical and scientific information regarding the study compound.
- Proactively engaging with investigators both during startup and ongoing throughout the study to maintain interest in and education about the study.
- Delivering education presentations on study protocol and milestones.
- Partnering with clinical operations and contract research organization to ensure surveillance, compliance, and effectiveness of study programs.
- Serving as a point of contact if necessary to relay site concerns to clinical colleagues.

Investigator Initiated Trials

Investigator initiated trials (IITs), also known as investigator initiated studies (IISs), investigator initiated research (IIR), or investigator sponsored trials (ISTs), are clinical studies initiated by KOLs, physicians, or other individual investigators and denote that such studies originate with an external investigator and are not solicited. In response to an unsolicited request, the MSL may hold preliminary, non-binding discussions about the investigators’ clinical trial proposal that is aligned with the company’s areas of interest. Under medical affairs supervision, MSLs may serve as the point of contact for the investigator and liaise with the medical team in the therapeutic area with regards to:

- Providing general information to the potential IIT applicant on the company’s concept submission process.
- Informing the investigator that the proposed concept may not be of interest to the company because it is outside the current therapeutic area medical plan/strategy.
  - MSLs should make it clear to the applicant that they are not responsible for the review and approval of study concepts and therefore cannot make any definitive statements in this regard.
Clinical Audits

The MSL may respond to unsolicited requests from HCPs for assistance in providing scientific information for the development of an audit or pathway redesign to improve healthcare quality and effectiveness initiatives. Such assistance is limited to published clinical or economic research, evidence-based guidelines, or company-related educational materials. MSLs should not make therapeutic recommendations for the development or adoption of a particular treatment or assessment protocols.

Health Economics and Outcomes Research

Health Economics and Outcomes Research (HEOR) provides important information for making healthcare coverage and access decisions.

- MSLs may present HEOR data to help healthcare payers determine if treatments work in the populations they serve. MSLs may provide analysis about the cost-effectiveness of a therapy to help payers make formulary decisions. While MSLs may be involved in formulary or payer presentations, typically other roles such as reimbursement or managed markets MSLs are involved in cost and reimbursement or access discussions. MSLs generally have approved medical materials or slides with HEOR data they can speak to, and any other aspects are usually referred to commercial or market access colleagues to address.

- In some circumstances, off-label therapy may be the standard of care by payers or clinicians, necessitating an accurate medical review of all relevant therapies.

- MSLs and other medical affairs professionals may not be compensated based on their success at getting drugs on formulary or based on increased sales or volume.
Insight Gathering

MSLs are the field-facing members of the medical affairs team and are responsible for bringing insights into the organization. MSLs may proactively collect insights formally or informally through their interactions with KOLs, HCPs, payers, and other stakeholders. Data protection laws and acts and corporate policies relating to MSL involvement in, contact with, or collection of individual data or information apply.

Collecting Insights

During scientific exchange, MSLs should listen for topics shared by KOLs or HCPs that may be of strategic interest to the company. Specifically, the following recommendations apply:

- MSLs may report questions asked, reactions to data presented, and other observations to their organization as insights for use in evolving strategy.
- MSLs may proactively ask questions to understand the HCP’s scientific point of view on topics to share as insights to their organization.
- MSLs may apply their scientific knowledge to collate and analyze the insights gained.
- Insights should be documented in the designated insight management system or CRM in a timely manner and should be worded to include the exact questions asked and the HCP’s comments. They should not be combined with the presentation of any topics.
- MSLs may work across the field medical/MSL team to identify trends and patterns in insights collected.
- MSLs may share insights with brand/strategic teams to assists with medical messages, medical plans, launch plans, and new materials.

Proactive Insight Surveys/Interviews

MSLs may gather both proactive and reactive insights on topics of interest or specific questions identified by the medical teams.

Any proactive insight survey should be approved internally by medical leadership and/or by a compliance business partner for guidance on proactive insight questions.
Advisory Boards

MSLs may participate in commercial advisory boards or they may lead medical-only advisory boards. Advisory boards should comply with regulatory requirements and legislation and are non-promotional in nature. The goal of an advisory board should be to understand the perspectives of the KOLs invited and never to influence their decisions.

Purpose of running an Advisory Board

- An advisory board is conducted for the benefit of the company. The purpose is to gain specific advice, feedback and/or understanding to support the planning and implementation of strategy and business activities. Advisory boards may cover on-label or off-label use of the company's products.
- The objectives of the advisory board should be clear and in line with the company's strategy.
- Typical areas covered by an advisory board include review of clinical data, marketing strategy, study design, development strategy, patients' management, funding, and access.
- Typically, the time the company's employees spend presenting (with slides) during the meeting should not be more than 30% of the total duration of the meeting, in order to leave the appropriate time for discussion by each participant.

KOLs selection criteria

- MSLs may recommend advisory board participants based on their scientific interest, expertise, and desire to provide insight. The KOLs participating in an advisory board should be selected based on their competencies and experience as demonstrated through their CVs.
- No commercial criteria can be allowed to influence the selection of advisory board participants.
- The number of advisors (ideally no more than 12) should not prevent each advisor from fully participating in the meeting.
- KOLs allowed to participate in an advisory board are specialists, general practitioners, pharmacists, hospital managers, nurses, or other professionals involved in the topics of the meeting.
- Generally, people covering institutional or political positions cannot attend such meetings.

Venue

- The venue (e.g. live, virtual, global, local) of the advisory board should align with the meeting purpose and objectives.
- The date, time, and duration of the meeting should be organized in order to allow the required advisors to participate and to spend no more than one day, including travelling (overnight accommodations should be minimized). Ideally, the participants should receive a minimum of 12 weeks' notice of the meeting in order to schedule it appropriately. This time frame is a recommendation, not a rule, given a variety of situations for ad boards. A modest venue should be selected according to local policies and/or SOPs and country regulations.
- The advisory board may be arranged in conjunction with a congress where the advisors are already present, but only if the advisors are chosen for their ability to provide advice and not only for their attendance of the congress itself.
Honoraria and contracts as per Section 6 of the PhRMA Code on Interactions with Healthcare Professionals:

- KOLs can be paid for their professional advice, but payment is not mandatory. Payments should be in line with company policy, appropriate for the HCP and the amount of advice given, and reflect real market value. An honoraria rate table is effective for managing different advisory boards and ensuring balanced pay.
- All members have to sign a contract before participating in the meeting and should also sign a registration sheet on the day of the meeting. Both documents are recommended to be retained for audit/inspection purposes.

Invitation

- The invitation to the advisory board meeting should contain the objective of the meeting, agenda, and the preparation required for the meeting.
- If the meeting concerns an unlicensed product or indication, careful wording may be necessary to state the purpose of the advisory board clearly without being promotional (i.e., no mention of the product).

Company attendees

- The MSL's participation in a commercial advisory board should be solely as a scientific expert to answer questions or present scientific information.
- An MSL may organize local scientific advisory boards as needed to achieve insight generation goals aligned with medical plans.
- Sales representatives and sales managers should not attend advisory boards.
- Other employees may attend in line with local regulations.
- Any company attendee should participate in a non-promotional role.

Meeting output

- Following the meeting, there should be a formal report. This should be circulated to the relevant internal functions and HCPs attending the meeting, if deemed necessary.
- A template for an advisory board report should be available at the company in order to ensure homogeneity in reporting important data (e.g. title of the meeting, date, venue, internal and external participants, agenda, comments on each topic, summary observation, or key outputs/actions).
- Every advisory board meeting should have “actions/next steps” in order to justify the meeting itself. Outcomes should be associated with the set objectives.
- Slide presentations from employees or KOL participants should be pre-approved, collected, and archived with all the documents required by local regulations.
Internal Support

Effectively engaging with internal stakeholders and commercial colleagues is a crucial activity for MSLs, and they are expected to collaborate with and serve as an integral part of a cross-functional team with company colleagues, including but not limited to sales, marketing, regulatory affairs, health economics, and market access roles.

The MSL may be expected to participate in internal meetings such as brand planning, long-range planning, and medical affairs planning. During such meetings, the MSL is expected to contribute to the development of brand and medical strategy through expertise and knowledge about the external healthcare environment, KOLs, and competitor intelligence.

Under no circumstances should MSLs be integrated with area or regional sales plans, targeting activities, or joint tactics for interacting with customers. However, they may be aligned in broad sharing efforts of appropriate information about KOLs, HCPs, or other key stakeholders.

MSLs may share local or regional medical plans with their appropriate business partners in order to better understand local educational needs (e.g. overview of medical initiatives, common medical information questions, medical insights, and practice trends excluding names of HCPs), provided commercial and medical do not allocate tactics and internal business partners respect the scientific, non-promotional role of the MSL.

MSLs may request/receive input from their commercial colleagues on the perceived medical needs of their local geographical area. However, commercial personnel cannot direct field medical activities, and the decision to incorporate commercial input into medical plans/activities lies with the medical affairs leadership. Medical plans should be specific and separate from commercial plans. Also, if using CRM systems, the medical/MSL area of the CRM must not be accessible to the commercial team.

Sales Representatives and MSL Role Clarification

The roles of MSLs and sales representatives are and must remain clearly distinct. The distinction of the roles needs to be communicated to all relevant internal stakeholders. In essence, MSLs engage in scientific exchange; they have non-promotional interactions that are objective, balanced, appropriately substantiated, free of promotional messages, and are scientific in tone and content. Sales representatives engage in on-label discussions with HCPs that are specific to marketed products using material approved for promotional use.

- MSLs and sales representatives can share when they met a given stakeholder and generally which topics were discussed.
- MSLs should not share specific details of the discussion, especially if it contained any unpublished off-label information.
- MSLs should not share any information on the perceptions of stakeholders.
- Specific sales numbers should not be shared.
- Tactics and plans for stakeholders’ engagement should not be shared proactively.
Internal Training & Mentoring

MSLs may act as a primary or secondary educator for members of the sales force in training them on disease state, therapeutic area, company products, scientific updates, reviews, etc. While imparting such training, the MSLs should use only pre-approved materials aimed exclusively for the purpose of training internal staff. Under no circumstances should members of the commercial team be trained in off-label indications for the company’s products. The training conducted by MSLs should contain factual scientific information about the given disease state or the company’s product that is fully aligned with the particular therapeutic area/brand strategy and in coordination with the training and medical affairs departments in the therapeutic area.

- MSLs may develop scientific training materials for use internally.
- MSLs may provide formal scientific training to other medical or non-medical teams.
- MSLs may respond to scientific questions from sales representatives; however, if the scientific question is from an HCP to the sales colleague, they need to follow the company’s policy.

Speaker Programs and Speaker Training Meetings

HCPs participate in company-sponsored speaker programs in order to help educate other HCPs about the benefits, risks, and appropriate uses of a company product. Speaker training is essential because in the U.S., the FDA holds companies accountable for the promotional presentations conducted by their speakers (as noted in Section 7 of the PhRMA Code on Interactions with Healthcare Professionals [see other relevant international guidance such as EFPIA]).

MSL activities at speaker training programs should be independent of substantive commercial influence. MSLs can present the clinical trial data, including the benefits and risks of the product. With the focus on educating speakers, MSL activity at speaker training programs is not promotional in nature.

MSLs should address questions from speakers while they are undergoing training on promotional presentations. During speaker training programs as well as one-on-one interactions with the speaker, MSLs can respond to questions following normal policies and procedures. MSLs can perform an essential role by ensuring speakers are fully informed about the product with all available scientific information.

MSLs may attend occasional speaker programs. MSL attendance at speaker programs can be perceived as promotional activity and may attract off-label requests, thus MSLs must exercise caution in this situation and follow local policy and procedures. While companies should periodically monitor speaker programs for compliance with FDA regulatory requirements (or other relevant authority) for communications on behalf of the company about its products, this audit should be conducted by compliance staff and/or in accordance with local policy and procedure.
Companies should:
- Define and establish clear guidelines as to how the MSL should provide speaker training support.
- Keep a documented record of MSL speaker training and the questions addressed.
- Keep documentation regarding off-label requests and how the request was delivered.
- Define and establish clear guidelines as to how the MSL should address off-label questions.
- Define and establish how the MSL speaker training role can be communicated to speakers.

Internal Projects

MSLs may participate in internal projects as a scientific expert or represent the voice of the KOL. As a representative on a strategic or project team, the MSL may:
- Provide scientific expertise.
- Share insights generated during KOL engagements and advise on their meaning.
- Provide a review of scientific materials for accuracy and fairness.

Summary

MSLs have a distinct role as the field-facing team representing a company’s medical affairs and medical objectives in a compliant and non-promotional manner. This document serves as a resource to guide the activities of MSLs, which include engaging KOLs, HCPs, and other healthcare providers in scientific exchange, collaborating on evidence-generation tactics, and providing internal support.
References


ANVISA. [https://www.emergobyul.com/resources/brazil/anvisa](https://www.emergobyul.com/resources/brazil/anvisa)


FDA. Food and Drug Administration. [https://www.fda.gov/](https://www.fda.gov/)


Interfarma. [https://interfarma.us/](https://interfarma.us/)

OIG. Office of Inspector General. [https://oig.hhs.gov/](https://oig.hhs.gov/)


