Medical Governance and Compliance
in the Pharmaceutical and MedTech Industries

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in the **Pharmaceutical** and **MedTech Industries**

Landscape

The Pharmaceutical and MedTech industries are highly regulated. Society at large—patients and HealthCare Professionals (HCPs)* in particular—expect companies to act appropriately and to comply with existing laws, regulations, and industry codes. Those in Medical Affairs need to understand these requirements to manage their activities in a legal, compliant, and ethical manner. The objective of this White Paper is to guide Medical Affairs personnel on the key components of the legal, regulatory, and industry codes of practice requirements which are applicable to Medical Affairs in Pharma and Medical Devices industries, and how to identify and mitigate risks. This paper also includes company control frameworks for compliance with the requirements through policies, processes (usually captured in Standard Operating Procedures [SOPs]), systems, training, monitoring, and audit.

Medical Governance and Compliance are underpinned by ethical guidelines for interactions between these industries and HCPs. These ensure that interactions and collaborations prioritise patient welfare, maintain professional integrity, and prevent undue influence or conflicts of interest. Government regulations and industry codes of practice provide the requirements, and Compliance functions use these to shape the advice they provide to staff in key areas such as:

- Transparency and Disclosure
- Independence and Objectivity
- Independent Medical Education and Sponsorship
- Research Collaborations
- Promotion and Marketing
- Conflict of Interest Management

Being aware of areas which can carry potential conflicts of interest, HCPs are thereby encouraged to transparently disclose these conflicts and maintain the integrity of their treatment decisions.

Disclose conflicts and maintain Integrity

* HCPs include professional individuals who are authorised to prescribe, purchase, supply, administer, or dispense medicines, vaccines, or medical devices.

Legal, Regulatory, and Compliance Frameworks

Regulations and the Role of Legal

Regulations are typically established by national and local regulatory bodies such as the Food and Drug Administration (FDA) and Federal Trade Commission (FTC) in the United States; the European Medicines Agency (EMA) covering the EU, Iceland, Norway, and Liechtenstein; and the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK. These regulatory bodies enforce rules that biopharmaceutical and MedTech companies must adhere to, with noncompliance resulting in penalties such as fines, regulatory audits, reputation damage, or business interruptions.

Corporate Integrity Agreements (CIAs) have been implemented as part of settlements between pharmaceutical companies and the U.S. government to address allegations of fraud and misconduct. These agreements, typically lasting 5 years, require companies to adopt stricter compliance measures, such as enhanced training, regular audits, and independent oversight. CIAs aim to curb unethical practices such as off-label marketing and kickbacks, forcing companies to operate with greater transparency and accountability. As a result, many pharmaceutical companies have improved their adherence to regulations, reducing the likelihood of future violations and fostering a culture of compliance.

Legal departments focus on the broader legal landscape governing the industry and individual conduct within the industry, aiming to minimize legal liability. Legal plays the role of interpreting the law and is involved in contracting and review of materials or business user cases.

Compliance in Medical Affairs

The role of Compliance in Medical Affairs is to manage operational risks, ensuring that the development of drugs, devices, and diagnostics is conducted legally and ethically. Compliance advises on business risk and mitigation and guides business advancement and innovation by identifying measures within the bounds of regulatory, legal, and company standards.

Medical Affairs and Commercial functions are bound by legal and regulatory frameworks that relate to the promotion of prescription medicines as well as data privacy and anti-bribery and anti-corruption measures, with considerations for legitimacy of intent, conflicts of interest, proportionality, and transparency. By adhering to these principles and regulations, the industry can maintain legal compliance and public trust while advancing medical knowledge and patient care.

Medical Governance

In some organizations, Medical Governance operates as a distinct function, while in others, it may be integral with Compliance or Risk Management. When established as a separate entity within the Medical Affairs function, Medical Governance usually collaborates closely with Compliance teams to interpret policies and provide strategic guidance, particularly in areas that lack clear industry standards or company procedures. This partnership is crucial in navigating ambiguous situations and ensuring that the company adheres to ethical and legal standards while continuing to innovate and deliver value to its stakeholders.

Medical Governance can play an integral role in shaping how a company conducts itself both internally and externally. It establishes a comprehensive governance framework that guides both Medical and Commercial teams. This ensures that teams make ethical, informed decisions that align with external requirements and adhere to the company's core values. By doing so, Medical Governance helps to safeguard the integrity of business operations while meeting the needs of key external stakeholders, including HCPs, decision-makers, patients, and the broader public. Additionally, a robust governance structure strengthens a company's focus on achieving its business objectives, addresses challenges with clarity, mitigates risks, and fosters trust within the industry. It also encourages a culture of compliance, guiding behaviors in a way that upholds ethical standards and regulatory mandates.

Regulations and Requirements for Key Areas of Risk

Promotion of Prescription Medicines

The following are examples of key regulatory agencies and do not necessarily reflect all existing regulations.

1 FDA

The U.S. Food and Drug Administration regulates prescription drug promotion to ensure that advertisements are not false or misleading and that they provide a fair balance of information about the benefits and risks. Since the FDA is one of the leading regulatory bodies aiming to protect public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices, its policies and regulations are widely referenced by other codes and regulatory frameworks.

2 EMA

The European Medicines Agency regulates promotional activities similarly, with a strong focus on the accuracy of information and prohibiting the promotion of prescription-only medicines to the general public.

3 MHRA

The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices, and blood components for transfusion in the UK. The MHRA is an executive agency, sponsored by the Department of Health and Social Care.

Data Privacy

The following are examples and do not necessarily reflect all existing regulations and requirements.

1. **The Health Insurance Portability and Accountability Act (HIPAA)** in the U.S. sets national standards for the protection of individually identifiable health information.

2. **The General Data Protection Regulation (GDPR)** provides comprehensive data protection and privacy rules in Europe, including for medical and health-related information.

Key Considerations

• **Legitimacy of Intent:** Data collection and processing must have a clear, lawful purpose, such as improving patient care or conducting legitimate medical research.

• **Conflicts of Interest:** Data privacy practices should avoid conflicts that could compromise the integrity or security of patient information.

• **Proportionality:** Data collection should be limited to what is necessary for the intended purpose.

• **Transparency:** Patients must be informed about how their data will be used, and consent must be obtained where required.

• **Protection of data and subjects' rights:** Ensure that subjects have the right of access to their data, the right to rectification, the right to erasure, the right to restrict processing, the right to data portability, the right to object, and the right not to be subject to a decision based solely on automated processing. Companies should have procedures on breach notification and a privacy policy in place.

Anti-Bribery and Anti-Corruption Measures

The following are examples and do not necessarily reflect all existing regulations and requirements.

1. **The Foreign Corrupt Practices Act (FCPA)** in the U.S., prohibits bribery of foreign officials and mandates accurate record-keeping.

2. **The UK Bribery Act** includes provisions against bribery in both the public and private sectors, imposing strict penalties for violations.

Key Considerations

• **Legitimacy of Intent:** Interactions between Medical Affairs staff and HCPs and officials must be for legitimate purposes, such as scientific exchange or medical education, and not for influencing purchasing decisions.

• **Conflicts of Interest:** Relationships between pharmaceutical companies and HCPs must be managed to avoid any actual or perceived conflicts of interest. Ensure that hospitality or other benefits (sometimes referred to as inducements) do not create conflicts of interest.

• **Proportionality:** Any financial support or benefits provided must be reasonable and not excessive.

• **Transparency:** Full disclosure of all payments, sponsorships, and benefits to HCPs and institutions is required to avoid any perception of impropriety.

Specific Requirements for Medical Affairs

The following are examples and do not necessarily reflect all existing Medical Affairs requirements.

1. **Continuing Medical Education (CME):**
   • **The Accreditation Council for Continuing Medical Education (ACCME)** sets standards for the independence of CME activities in the U.S., requiring that these are free from commercial bias.

   • Good CME Practice (gCMEp) ensures that CME activities in Europe are independent, evidence-based, and designed to improve medical practice.

   • Education activities that are not considered CME (e.g., HCPs providing educational content, unaccredited education programs, grants, sponsorships, patient education programs) are governed by the codes of practice and other regulations.

2. **Scientific Exchange:**
Medical Affairs teams are often involved in scientific exchange activities, which must be clearly differentiated from promotional activities and adhere to guidelines ensuring that they are nonpromotional, evidence-based, and conducted with scientific rigour.

3. **Scientific Publications:**
The International Committee of Medical Journal Editors (ICMJE) has established standards for the conduct, reporting, editing, and publication of scholarly work in medical journals. The ICMJE expects authors to ensure that they have met the requirements of their funding and regulatory agencies regarding aggregate clinical trial results.

4. **Research Activities:**
GxP is a collection of quality Good Practice guidelines and regulations created to ensure that bio/pharmaceutical products are safe, meet their intended use, and adhere to quality processes during clinical development, manufacturing, storage, and distribution. GxP includes Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), and Good Laboratory Practice (GLP).

US REGULATORY AGENCIES AND CODES SUMMARY

AGENCY OR CODE	PURPOSE
The U.S. Food and Drug Administration (FDA)	Regulates prescription drug promotion to ensure that advertisements are not false or misleading and that they provide a fair balance of information about the benefits and risks
Pharmaceutical Research and Manufacturers of America (PhRMA)	Sets out guidelines for interactions with HCPs, including restrictions on gifts and promotional activities in the USA
The Health Insurance Portability and Accountability Act (HIPAA)	Sets national standards for the protection of individually identifiable health information.
The Foreign Corrupt Practices Act (FCPA)	Prohibits bribery of foreign officials and mandates accurate record-keeping.
The Accreditation Council for Continuing Medical Education (ACCME)	Sets standards for the independence of CME activities in the USA, requiring that these are free from commercial bias.

Table 1. US Regulatory Agencies and Codes Summary

Industry Codes of Practice

In the context of Compliance and Medical Governance, industry codes of practice around the world play a crucial role in guiding the behaviours as well as the ethical and compliant conduct of pharmaceutical and MedTech companies. The scope of the European and international codes is for prescription-only medicines and vaccines and does not include nonprescription medicinal products. This section explores the reason for these codes, how they add value and reduce risks, and how these codes should be interpreted in the context of Medical Affairs activities. It will also compare key regional and country-specific codes, examining their similarities, differences, and areas where they may be silent.

Regional Pharmaceutical Codes

Pharmaceutical Research and Manufacturers of America (**PhRMA) Code**: This code sets out guidelines for interactions with HCPs, including restrictions on gifts and promotional activities in the U.S. **PhRMA's Principles on Conduct of Clinical Trials Communication of Clinical Trial Results** help assure that clinical research conducted by U.S. biopharmaceutical companies is carefully conducted and that meaningful medical research results are communicated to HCPs and patients.

The European Federation of Pharmaceutical Industries and Associations **(EFPIA) Code** provides a code for ethical promotion, emphasizing transparency and the appropriate use of promotional materials in Europe.

The International Federation of Pharmaceutical Manufacturers & Associations **IFPMA Code of Practice 2019 | IFPMA** represents the innovative pharmaceutical industry at the international level and in official relations with the United Nations.

Codes of Practice

Why Do These Codes Exist?

1. Ensuring Ethical Conduct: The primary purpose of these codes is to ensure that pharmaceutical and MedTech companies conduct their activities ethically. The codes are typically driven by HCPs to set the standards they expect from pharmaceutical companies. They include interactions with HCPs, patients, and other stakeholders.

2. Promoting Transparency: These codes promote transparency in the marketing and promotional activities of these companies. Transparency is critical in building trust among HCPs, patients, and the general public.

3. Protecting Patients and HCPs: By setting clear guidelines, these codes protect patients and HCPs from misleading information and unethical practices. This is crucial in ensuring that medical decisions are based on accurate and reliable information.

4. Regulatory Compliance: Adhering to these codes helps companies comply with legal and regulatory requirements, reducing the risk of legal repercussions and enhancing their reputation.

5. Distinguishing Between Promotional and Non-Promotional Activities: Understand the fine line between promotional activities and those aimed at scientific exchange or education.

6. Providng Guidance and Interpretation of Legal and Regulatory Requirements: Some legal and regulatory requirements are not sector- or scenario-specific or open for interpretation. Industry codes can provide best practice guidance.

Value Addition and Risk Reduction

1. For Pharma and MedTech Companies:
- **Reputation Management:** Adherence to these codes enhances the reputation of the companies, making them more trustworthy in the eyes of healthcare providers and patients.

- **Legal Protection:** Compliance with these codes helps companies avoid legal issues and fines associated with noncompliance.
- **Market Access:** Ethical conduct and compliance can facilitate smoother market access and partnerships with other organizations.

2. For HCPs:
- **Accurate Information:** Ensures that the information provided by pharmaceutical companies is accurate and not misleading, aiding in better decision-making.
- **Trust:** Builds trust between HCPs and pharmaceutical companies, fostering better collaboration and patient outcomes.

3. For Patients:
- **Informed Decisions:** Provides patients with reliable information, allowing them how to make informed decisions about their health.
- **Safeguarding Information:** Companies adhere to the code and thereby add a level of trust and oversight via best practices and industry standards.

Interpretation of Codes With Respect to Medical Affairs Activities

Medical Governance and Compliance personnel must interpret existing codes in a way that aligns with both promotional and nonpromotional activities. While these codes primarily focus on promotional activities, Medical Affairs activities, such as scientific communications, educational events, and advisory boards, must also adhere to these ethical standards. It should be noted that local codes or regulations sometimes vary from those of the regional codes; thus, it is important to follow the stricter requirements in the event of differences.

Key Similarities and Differences in Regional Codes

1. Ethical Principles: Most regional codes, such as PhRMA (U.S.), IFPMA (international), and EFPIA (Europe), share common ethical principles, including integrity, transparency, and protection of patients' well-being.

2. Differences in Focus:

- **Direct-to-Consumer (DTC) vs. HCPs:** In the U.S., PhRMA guidelines allow for DTC advertising of prescription medicines, whereas EFPIA and IFPMA codes restrict promotional activities to HCPs only.

- **Cultural and Regulatory Variations:** Different regions may have varying cultural attitudes towards pharmaceutical promotion, influencing the stringency and focus of their codes.

Country-Specific Codes
The following are examples of important country-specific codes.

1. UK: The Association of the British Pharmaceutical Industry (ABPI) Code is known for its stringent requirements on transparency and ethical interactions with HCPs and patients.

2. Australia: Similar to ABPI, Medicines Australia emphasizes ethical promotion and transparency but has specific provisions reflecting Australian health care regulations and practices.

3. Japan: The Japan Pharmaceutical Manufacturers Association (JPMA) code focuses on ethical promotion, with particular attention to the cultural context of Japan.

4. Canada: Health Canada's guidelines focus on ensuring the safety and efficacy of marketed products, with stringent regulations on promotional activities.

The IFPMA Global Code Comparison Report contains a detailed comparison of the different industry codes by country.

Activities Not Well Supported by Codes

Activities which are not specifically covered by the regional codes may be of particular concern in the case of local codes, where such activities may not be mentioned. These include:

1. Patient Support Programs: These programs often fall into a grey area, as they are intended to provide support but can be perceived as promotional. Clearer guidelines may be needed to delineate acceptable practices in this area.

2. Disease Awareness Campaigns: Disease awareness campaigns aimed at the general public are important but are not always wellcovered by existing codes. These campaigns need to be conducted in a way that provides accurate information suitable for the general public without being promotional.

3. Social Media Activities: The manner in which pharmaceutical and MedTech companies communicate about prescription medicines on social media channels has become of increasing concern to regulatory and advisory bodies. In 2023, the ABPI amended its code with a Social Media Guidance section to address this issue.

4. Artificial Intelligence (AI): It has also been acknowledged within the industry that AI is a fast-evolving area which will require significant dynamic and adaptive learning to apply appropriate and well-informed guidelines which do not currently exist specifically for Medical Affairs activities. However, most general AI regulatory frameworks are centered around risk mitigation, and therefore the principles can be applied to medical affairs.

Application of Regulations and Codes in Practice

Nonpromotional Medical Activities

Medical Governance and Compliance personnel play a critical role in ensuring that medical activities adhere to regulatory codes of practice, thereby maintaining the integrity and trustworthiness of interactions between the pharmaceutical industry HCPs or the public. These regulations are designed to prevent promotional activities disguised as medical or scientific information dissemination. To ensure robust ethical decision-making in the execution of Medical Affairs activities, Medical Governance applies various strategies and guidelines to distinguish nonpromotional from promotional activities, whilst Compliance ensures standards, laws, and regulations are complied with through monitoring nonpromotional activities. While promotion and marketing is the role of Commercial and not Medical Affairs, the latter does have a role in the review and approval of promotional materials. The following sections outline how these principles are applied across common Medical Affairs activities.

Advice-Seeking

Regulatory Context:
- **IFPMA Code:** Interactions with HCPs should be intended to provide scientific or educational information and should not be designed to promote specific products.
- **EFPIA Code:** Any advice sought should be relevant, legitimate, and necessary, ensuring that HCPs are not used as a conduit for promoting products.

Practical Application:
- **Advisory Boards:** When organizing advisory boards, the agenda must focus on genuine scientific inquiry and the collection of advice and insights for legitimate Medical Affairs activities. For instance, a meeting designed to understand the clinical experiences of HCPs within a certain therapeutic area, rather than discussing the benefits of a specific drug. In general, it is acceptable for advisory boards to seek advice on the risk/benefit ratio of a new medicine based on the clinical data, but this must not be in any way promotional in intent or execution.

- **Example:** An advisory board convened to discuss the challenges of managing diabetes patients might seek input on patient adherence to insulin therapy and must avoid promoting a new insulin product.

- **Surveys and Questionnaires:** These can be administered via online, face-to-face, or telephone methods and aim to gather information from study subjects (e.g., patients, carers, HCPs) directly. Topics can range from disease management, unmet needs, awareness, preference, or patient care practices with or without referencing specific disease, products or brands.
  - **Example:** A survey distributed to oncologists online to understand the prevalence of different treatment protocols for breast cancer, without mentioning any branded therapies.

Peer-Review Publications

Regulatory Context:
- **PhRMA Code:** Publications must be scientifically rigorous and devoid of promotional bias.
- **EFPIA Code:** Scientific publications should be objective, fair, and balanced and should not serve as a medium for product promotion.
- **ICMJE:** Publications must meet certain criteria for authorship, clinical trial parameters, as well as preparation and formatting.

Practical Application:
- **Manuscript Development:** Articles for peer-reviewed journals must focus on data and findings from well-designed studies without overstating the benefits or minimizing the risks associated with a product.
  - **Example:** A publication detailing the results of a clinical trial for a new antihypertensive drug should present both the efficacy data and any adverse events observed during the trial.

- **Authorship and Transparency:** All contributions must be clearly attributed, and any involvement of the sponsoring company should be transparent.
  - **Example:** If a pharmaceutical company funds a study, the publication should disclose the source of funding and ensure that authorship reflects the true contributors to the work, in accordance with the ICMJE guidelines.

Medical Education

Regulatory Context:
- **IFPMA Code:** Educational events and materials must be nonpromotional and aimed at enhancing medical knowledge and patient care.
- **EFPIA Code:** Medical Education activities should not promote specific products and should focus on broader therapeutic or disease state education.

Practical Application:
- **Continuing Medical Education (CME) Programs:** These programs should cover topics of medical importance without focusing on a company's product portfolio. Content must be balanced and presented by independent experts.

- Internationally, Medical Education can be classified as Independent and Non-Independent Medical Education or as Independent Medical Education and Company-Led Education, since not all Medical Education activities can be classified as CME (with associated credits awarded). Independent Medical Education typically covers both accredited (i.e., CME) and non-accredited Independent Medical Education.
  - **Example:** A CME event on the latest advancements in cardiology that includes discussions on various treatment options for heart failure, presented by recognized cardiologists, without emphasizing any particular drug.

- **Educational Materials:** Brochures, slide decks, and other educational materials provided to HCPs should offer unbiased information on disease states, treatment guidelines, and emerging medical research.
  - **Example:** An educational booklet on managing rheumatoid arthritis that includes comprehensive information on lifestyle modifications and pharmacologic and nonpharmacologic interventions, without highlighting any specific medication.

Key Principles for Medical Governance and Compliance

To ensure that all medical activities remain compliant and nonpromotional, the following principles must be rigorously applied:

- **Clarity and Legitimacy:** Information must be clear and relevant to the intended audience. For instance, patient education materials should be written in accessible language and focus on general disease management.
- **Up-to-Date Information:** Ensure all data and materials are current and based on the latest scientific evidence. Regularly update materials to reflect new research findings.
- **Fairness and Objectivity:** Present balanced views, including both benefits and risks of medical treatments, and avoid any exaggerated claims.
- **Substantiation:** All statements must be backed by robust scientific evidence and referenced appropriately.
- **Transparency:** Disclose any company involvement or sponsorship in all medical activities and publications.
- **Respectfulness:** Avoid content that could be offensive or disparaging to any individuals, groups, or organizations.

By adhering to these principles and leveraging the regulatory frameworks provided by industry codes, Medical Affairs, Medical Governance, and Compliance personnel can effectively navigate the fine line between providing valuable medical information and inadvertently engaging in promotional activities. This ensures that their communications remain ethical, credible, and aligned with the overarching goal of improving patient care.

Control Framework

Compliance Culture and Framework [1]

Maintaining a robust compliance culture within Medical Affairs organizations in the pharmaceutical and MedTech industries is not just prudent, it is a strategic imperative. This culture must be nurtured through strong "tone from the top" leadership, where leaders exemplify governance and compliance standards and foster an environment where employees feel empowered to voice concerns without fear of retaliation.

To help navigate the complexities of regulations and codes, companies develop comprehensive policy and procedural documents, such as SOPs, and train staff accordingly. Clear delineation of roles, accountabilities, and responsibilities, especially between Commercial and Medical functions, is crucial to managing robust ethical application of knowledge and compliant execution in promotional and scientific activities, respectively. Additionally, effective monitoring, auditing, and disciplinary procedures are essential to ensure adherence to these processes, thereby safeguarding the organization, HCPs, and the patients who depend on their medicines.

A company's compliance framework must begin with a thorough consideration of the relevant legal, regulatory, and industry codes. These form the backbone of the compliance structure and are modified by various environmental factors and the company's risk tolerance levels. It is crucial to integrate compliance into the organizational culture, ensuring that all employees understand and adhere to the requirements. This leads to a compliant and ethical business operation, minimizing risks and enhancing the company's reputation and trustworthiness in the eyes of regulators, HCPs, and patients.

Risk Mitigation

Understanding and managing compliance-related risks is a cornerstone of an effective compliance program. Companies must conduct comprehensive risk assessments to identify both emerging and inherent risks. This involves documenting potential risks, interviewing key business stakeholders to grasp the organization's priorities, and often ranking these risks using a scoring system. Once identified, Risk Mitigation Plans are developed to outline specific controls and actions needed to mitigate these risks, along with assigning process owners responsible for their management. This proactive approach helps in anticipating potential issues and implementing measures to prevent noncompliance.

Policies, Procedures, and Systems

Policies and procedures are vital tools for communicating the principles, standards, and requirements that address identified risks. Policies provide the principles that outline the organization's stance on compliance issues, while procedures offer detailed instructions on how these policies should be implemented. Additional quick reference guides can help employees perform specific tasks in line with compliance requirements. Together, these documents ensure that all staff members are well informed about what is expected of them and how to apply their knowledge to empower them to execute their daily activities based on robust ethical and compliant decision-making.

Supporting systems play a crucial role in reinforcing compliant and practical processes. These systems can range from simple databases to sophisticated software platforms that manage and document compliance of activities. For instance, an approval process for promotional materials might leverage a system that tracks submissions, reviews, and approvals, ensuring that all promotional content complies with regulatory standards before reaching HCPs. Such systems not only enhance the compliance of processes but also provide an audit trail that can be invaluable during regulatory inspections or internal audits.

Training

Effective training is essential for ensuring that all relevant employees and third-party contractors understand and adhere to a company's policies and procedures. Training methods can vary, from traditional classroom sessions to online courses and interactive workshops. It's important to tailor training programs to the audience's needs, making sure that the content is relevant and engaging. Regular training updates are also necessary to keep up with changes in regulations and company policies and procedures. By investing in comprehensive training, companies can significantly reduce the risk of noncompliance and promote a culture of continuous improvement.

Testing and Auditing

To verify that key processes are functioning as intended, regular testing and auditing are crucial. These activities involve reviewing practices, identifying any deviations from established procedures, and assessing the effectiveness of risk-mitigation measures. Based on the audit results, Compliance management personnel can determine if any changes are needed to policies, systems, or training programs. This ongoing cycle of monitoring and improvement ensures that the company's compliance framework remains robust and responsive to new challenges.

For a compliance framework to be truly effective, it must be supported by a strong compliance culture that is promoted by leadership at all levels. This culture should emphasize the importance of adhering to legal, regulatory, and industry codes and encourage open communication and continuous improvement. By integrating related codes, managing compliance risks, developing clear policies and procedures, leveraging supporting systems, providing comprehensive training, and conducting regular testing and auditing, companies can create a sustainable compliance framework that protects their organization, HCPs, and patients. The continuous cycle of these components ensures that compliance remains a dynamic and integral part of the business strategy.

Effective training and continuous **Improvement**

Integrating a Compliance Program Into Medical Affairs Activities

Considering all of the interrelated components, embarking on the journey from recognizing the need for a compliance framework within Medical Affairs to the successful implementation of such a program can seem daunting. This section aims to provide a broad guide for integrating a compliance program into Medical Affairs activities.

Strategy

Compliance activities are largely driven by the company's strategic goals, focusing on how these activities can advance those goals. Integrating a compliance strategy into Medical Affairs should include benchmarking against industry standards. Starting with these standards, the strategy development continues with risk assessments across product lines, therapeutic areas, and geographies. Identifying these risks helps the Compliance department anticipate and prepare for challenges that the Medical Affairs organization may encounter.

Governance

Creating governance groups, including one specific to Medical Affairs, helps to support decision-making and ensure standards for the implementation of key Medical Affairs activities. It ensures that Medical Affairs activities align with compliant practices, such as permissible interactions between Medical and Commercial teams and guidelines for research funding.

Develop and Communicate Operational Procedures

Many companies mistakenly skip directly to creating SOPs without completing the strategic and policy steps that define the SOPs' purpose and streamline their creation. Once these have been determined, however, succinct yet comprehensive SOPs for the activities identified in the risk assessment should be created. The communication and information-sharing strategy to minimize confusion and potential discord between Medical Affairs and internal and external partners must also be considered.

Monitor and Review Procedures to Support Medical Affairs Activities

The practice of Medical Affairs and the health care and societal ecosystems are not static. Initial strategies and SOPs should be reviewed after 12 to 24 months to monitor whether earlier decisions and objectives are delivering the expected outcomes. Ideally, SOPs should mitigate risks while encouraging innovation. At times, these two factors may seem opposed, but it is often possible to evolve SOPs to both minimize risk exposure and drive business outcomes aligned with patient priorities.

Conclusion

Policies, procedures, and industry codes of practice in Medical Affairs are essential for ensuring legal and ethical conduct, transparency, and protection for all stakeholders involved. While these add significant value and reduce risks, Medical Governance and Compliance personnel must carefully interpret and apply them to ensure all activities, both promotional and nonpromotional, adhere to these standards. Comparing regional and country-specific requirements in these areas highlights both the common ethical foundations and the unique challenges each country faces. Addressing the gaps in patient support programs, disease awareness campaigns, and application of AI can further enhance the effectiveness and relevance of these areas of Medical Affairs. The codes and regulations will continue to evolve, and there are already signs that they will become more principle-based and less prescriptive.

Reference

[1] Lloyd, M, Santos, J. Chapter 16 - Compliance. *Medical Affairs: The Roles, Value and Practice of Medical Affairs in the Pharmaceutical and Medical Technology Industries.* Medical Affairs Professional Society, 2024.

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