epsilon
life sciences

CLIENT ALERT

A Reminder on Compliance Considerations in Medical Affairs

> "Medical Affairs has a Central Role to Play in Building Trust Between Doctors and Healthcare Stakeholders and the Pharmaceutical Industry." – Cesar Sanz Rodriguez, Associate Vice President, Medical Affairs Lead Mid-Europe, Eastern Europe, Middle East & Africa Regions, MSD, April 3, 2019 in a discussion with the European Medical Journal

Medical Affairs plays a critical role in the life sciences industry by bridging the gap between scientific research and clinical practice. Medical Affairs professionals ensure Healthcare Professionals (HCPs) have access to accurate and up-to-date medical information about products, while maintaining a non-promotional cadence throughout the interactions. Simultaneously, Medical Affairs plays an important role in communicating valuable information obtained from their interactions with HCPs and other external stakeholders back to the company. Given the highly regulated nature of the life sciences sector, there are several compliance considerations that Medical Affairs professionals must carefully navigate to ensure ethical and legal practices when engaging in a range of activities, including interacting with HCPs, disseminating medical information, and conducting clinical trials.

1. Engagement and Partnerships with HCPs

Scientific Exchange vs. Promotion: Medical Affairs professionals engage in scientific exchange to provide accurate information about their products to HCPs. However, they must avoid crossing the line into discussions that could be construed as promoting a product. Clear boundaries between sharing scientific information and promoting products are crucial for navigating the complex landscape of interactions between Medical Affairs and Sales. Companies should establish policies and SOPs along with real-world, role-based scenario training to ensure Medical Affairs personnel understand where their role ends and a commercial role may begin.

Digital and Social Media: In the age of digital communication, special attention must be given to online interactions and social media. Companies are turning to digital platforms to communicate with HCPs through providing medical education, remote training, and virtual discussion forums. Life sciences companies should closely monitor the information shared through these platforms and control access to these platforms based on the type of information being shared. The risk of inappropriate direct-to-consumer marketing is increased via these platforms. Additionally, HCPs may be using social media as the source of clinical information and may be proactive in promoting patient health education through these platforms. Medical Affairs professionals should be mindful of the type of content your organization is sharing on social media platforms and how this may be absorbed and used by HCPs and patients alike.

Advisory Boards and Key Opinion Leader (KOL) Relationships: Collaborations with KOLs and advisory boards must be transparent and guided by scientific integrity. The selection of KOLs should be based on expertise rather than promotional potential, all payments should be based on fair market value, and financial relationships must always be disclosed (as is required by law in most countries/ localities).

KOL relationships must be transparent and managed carefully to prevent undue influence on medical decisions, avoid conflicts of interest, and avoid the perception or reality of promotion.

Compliance Training and Monitoring: Regular training on healthcare compliance is essential for all Medical Affairs personnel to ensure a thorough understanding of the Company policies and procedures and the regulatory landscape. Country, state, and federal regulations and legislation around healthcare compliance are constantly evolving, making it crucial to stay updated.

2. Dissemination of Medical Information

Promotional Regulations: Life sciences organizations must adhere to strict regulations governing the promotion of pharmaceutical and medical device products. Medical Affairs teams must avoid having proactive off-label conversations with HCPs or sharing misleading information. Any off-label inquiries from HCPs should follow a process for responding to the inquiry in a reactive manner.

Case Study

In 2013, Johnson & Johnson settled a lawsuit with the U.S. Department of Justice for $2.2 billion. The settlement resolved allegations that Johnson & Johnson marketed the antipsychotic drug Risperdal for off-label uses not approved by the FDA and paid kickbacks to physicians and nursing home pharmacies to promote its usage. This case involved inappropriate medical affairs attendance at company sponsored events.

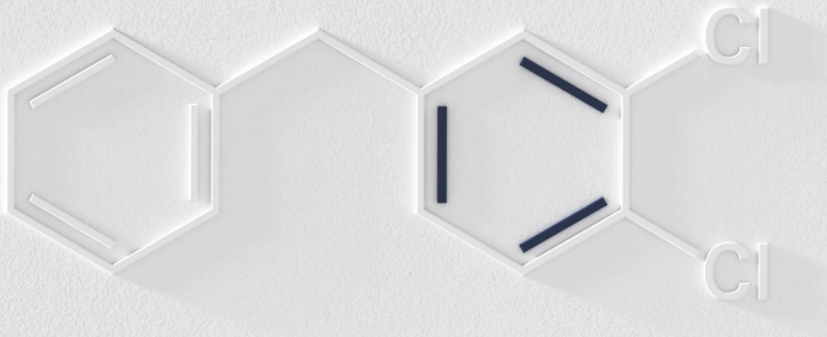
Material Review and Approval Processes: All promotional and scientific materials, whether internal or external, should undergo a rigorous review and approval process to ensure compliance with Company policies and FDA regulations. Medical Affairs plays an important role in ensuring promotional materials used by the commercial teams accurately reflect the product's approved indications, risks, and benefits.

Any scientific information shared must be based on sound scientific evidence and clinical data, as misleading or inaccurate information can lead to severe legal and reputational consequences and put patients at risk.

Case Study

GlaxoSmithKline (GSK) settled with the U.S. Department of Justice for $3 billion in fines for promoting certain drugs (e.g., Paxil, Avandia, and Wellbutrin) for unapproved and off-label uses and failing to report safety data. The settlement included allegations that GSK provided misleading information to HCPs about the safety and efficacy of its products and improperly prepared, published, and distributed misleading medical journal article.

Post-Marketing Surveillance: Medical Affairs continues to monitor product safety and efficacy even after a product is on the market. Ensuring that adverse event reporting, labeling updates, and safety communications are managed effectively is essential for ongoing compliance.



3. Generation of Clinical Evidence

Regulatory Guidelines and Laws: Medical Affairs professionals must adhere to a multitude of regulatory guidelines and laws that govern the ethical conduct of clinical trials, including Good Clinical Practice (GCP) guidelines, to ensure the safety of participants and the integrity of the data collected.

Data Integrity and Transparency: The pharmaceutical industry relies heavily on clinical data to support product claims. Medical Affairs must ensure all data is transparently presented to HCPs, regulatory agencies, and the public. Any manipulation or misrepresentation of data can lead to severe consequences. This also applies to any spend related to interactions of HCPs or healthcare institutions where government mandated transparency reporting is required.

Recent Developments in Technology and Regulations: The rapid evolution of Artificial Intelligence (AI) is propelling medicine and healthcare forward but comes with many new risks for organizations to consider. AI can be used to assist in the prediction of risk for specific health conditions or outcomes, enhance patients' ability to self-manage diseases at home, and streamline the accessibility of clinical data to name just a few of the many use cases in the industry. However, these benefits come with added risk as there is the potential for misuse of AI tools, as well as data biases and privacy concerns associated with the tool.

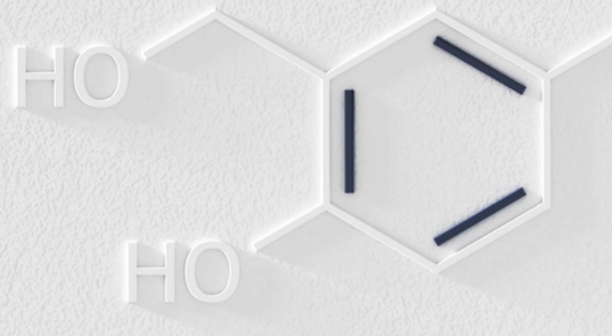
Numerous regulatory measures have been instituted to address the growing utilization of AI, particularly within the healthcare sector. The European Union (EU) recently implemented the European Union AI Act as the world's first comprehensive AI law to minimize risk associated with AI usage.

The EU AI Act establishes criteria for safeguarding data privacy, validating algorithms, ensuring data accuracy, and verifying AI outputs through human validation to mitigate potential risks.

Privacy and Data Protection: Medical Affairs professionals handle sensitive patient and HCP information. Compliance with data protection regulations, such as GDPR in Europe or HIPAA in the United States, is crucial to safeguarding patient privacy and maintaining trust.

Compliance considerations are integral to the functioning of Medical Affairs within the pharmaceutical industry. Adhering to ethical and legal guidelines not only safeguards public health but also maintains the industry's credibility and reputation. A robust compliance framework ensures that Medical Affairs professionals can effectively communicate medical information while upholding the highest standards of integrity and transparency.

Epsilon Life Sciences professionals have served the industry for over two decades with Medical Affairs strategy and compliance, supporting the development and implementation of fundamental roles and responsibilities relative to the commercial side of the organization. We have also developed Medical Affairs-focused policies and procedures and supported implementation through training, auditing, and monitoring. Bringing our collective experience as Medical Affairs and commercial professionals in the industry together with our enforcement experience, we offer unique solutions and strategies while mitigating healthcare compliance risk within the function.



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