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life sciences

CLIENT ALERT

Unveiling the Nexus: Exploring Compliance Challenges in Social Media Engagement within the Life Sciences Industry

Life sciences manufacturers face unique challenges when it comes to using social media beyond the standard complexities in the industry due to the strict regulations and compliance requirements. At the same time, many companies are relying more and more on social media to maintain share-of-voice and support direct-to-patient advertising (in the United States and New Zealand). When used correctly, social media can be a powerful tool and opportunity for a manufacturer. However, usage brings risk. Thankfully, there are numerous ways to manage and mitigate that risk.

Epsilon Life Sciences has served as the Independent Review Organization to a number of companies under a Corporate Integrity Agreement, where the Office of Inspector General Monitor exercised the right to select additional areas for review – social media has been a recuring theme.

As our team has evaluated company governance, policies, and procedures associated with social media, several considerations we have contemplated are worth keeping in mind:

Adherence to Regulatory Guidelines

Risk – Life sciences manufacturers must ensure that their social media activities comply with regulations set by authorities such as the Food and Drug Administration (FDA) in the United States or the European Medicines Agency (EMA) in Europe. These regulations include guidelines for advertising (including direct-to-consumer), labeling, and promotion of products. In addition, industry associations have set expectations and enforcement requirements related to social media use.

Social media is often not localized. Social media activity meant for a specific market may be viewable or shared across the globe, which then can broaden the scope of regulatory authorities governing the activity.

Management of the Risk – Manufacturers can reduce the risk by limiting who is authorized to post on the organization's official social media accounts, as well as developing review processes where qualified individuals can consider the appropriateness of the activity and disclosures against various regulations. Manufacturers can establish 'standard responses' to posts on company sites and thresholds for removing public posts on the company site.

Managing Adverse Events

Risk – Life sciences manufacturers have a responsibility to promptly report and manage adverse events associated with their products. For example, does the manufacturer have a responsibility to monitor all the content related to the manufacturer or a product on social media? Or is that limited to content created by the manufacturer and posts on the manufacturer's site? Or are reporting obligations limited to what a manufacturer or representative becomes aware of?

Management of the Risk – When using social media, manufacturers should have mechanisms in place to monitor and respond to any reports of adverse events that may be shared by users, at the very least on manufacturer-sponsored sites.

Transparency and Disclosure

Risk – Social media posts that include reference to a relationship and the nature of the relationship is not clearly disclosed results in the risk of a perceived conflict of interest.

Management of the Risk – It is important for manufacturers to clearly disclose their identity and affiliation when engaging in social media activities. Any connections or relationships with healthcare professionals, institutions or patient advocacy groups should be transparently disclosed to avoid any perceived conflicts of interest. Third parties (e.g., paid speakers, patient spokesperson) also have a duty to disclose their relationship with the manufacturer.

Handling User-Generated Content

Risk – Social media platforms often involve user-generated content, such as comments or testimonials. As the content is not controlled by the manufacturer, such content heightens the risk in a variety of areas including compliance with privacy and regulatory requirements as well as appropriate promotion of a product. For example, should the ability for comments on a social media activity always be turned off?

Management of the Risk – Manufacturers must be vigilant in monitoring and moderating such content to ensure that it doesn't lead to privacy concerns, violate regulatory requirements, or promote off-label uses of their products.

Fair Balance and Risk Information

Risk – When discussing their products on social media, manufacturers should ensure that they provide a balanced view of the benefits and risks. They should avoid making exaggerated claims or misleading statements that could potentially misinform or deceive the public. For example, how does a manufacturer ensure a balanced view within the confines of the different social media platforms (e.g., character limitations)?

Management of the Risk – Social media sites should be reviewed and approved for the content, platform, usage, and related setting prior to any posting. The added challenge for each manufacturer is doing this review in a timely and efficient media in order to keep up with the pace of social media. The use of links and the creation of template responses can help.

Freedom of Speech

Risk – The line between personal communications and what can be controlled by a life sciences manufacturer is not always clear on social media. Social media can make private comments public (e.g., the sharing of a screenshot).

Management of the Risk – A manufacturer needs to have clear policies, guidance, and education on what is private and how to make social media private.

Employee Training

Risk – Employees are often proud of the organizations they work for and may want to share good news about the manufacturer. However, if done inappropriately, doing so can expose a manufacturer to unnecessary risks. For example, could it be perceived as promotion if an employee likes a post about a news article related to a yet-to-be-approved indication?

Management of the Risk – Manufacturers should ensure their employees and agents of the company have clear, written standards and training related to social media. Even employees that have job responsibilities outside of social media should understand the implications of their social media actions, such as posting, sharing, and commenting, including the potential for the perception of representing the company. Before key events such as company announcements, press releases, and conferences, reminders about what an employee can and cannot do on social media related to the event can help prevent misusage.

Monitoring

Risk – Manufacturers are held accountable for what appears on company sponsored sites.

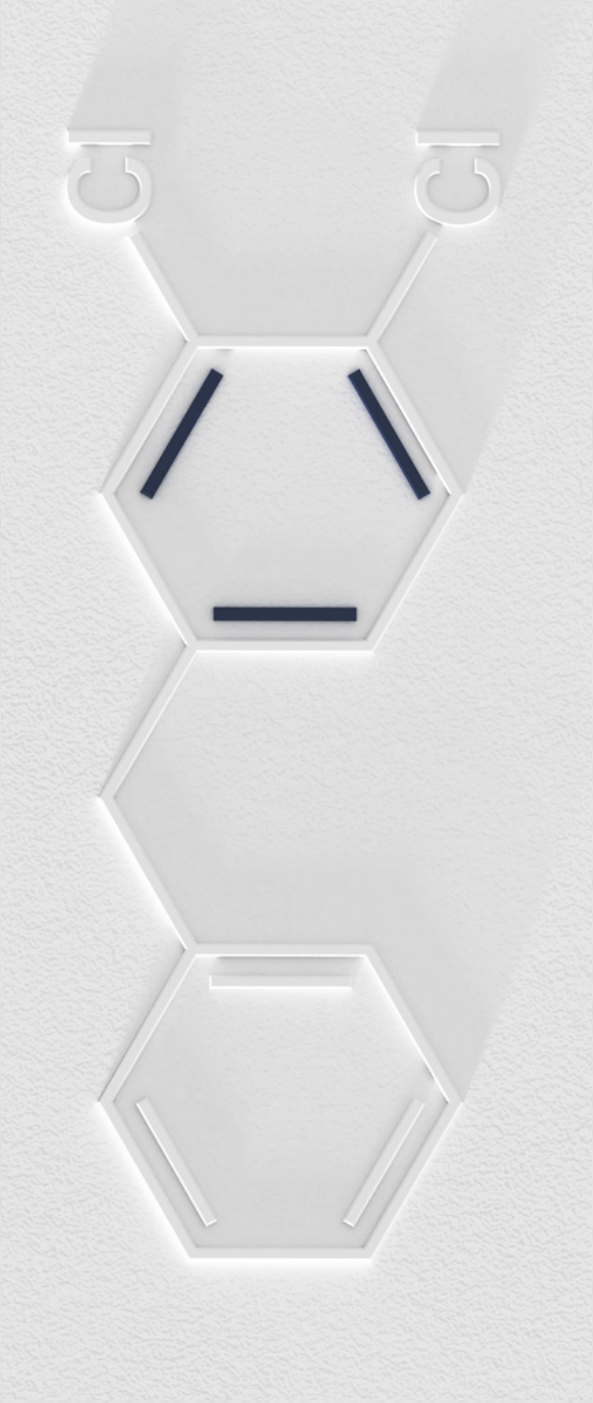
Management of the Risk – A manufacturer should have a formalized social media monitoring plan in place. The manufacturer must monitor the content of social media sites in particular for company sponsored sites. Utilizing web scraping tools can help in performing more efficient oversight and detecting content to monitor. Related corrective actions should be codified.

Access, Record-Keeping, and Archiving

Risk – Manufacturers should develop processes to ensure their ability to access records, document and record social media activities, and to archive the documentation. It is important to have records of social media activities for audit purposes or, if required, to demonstrate compliance with regulations. In addition, when there are not proper security protocols in place, there is a risk of hacking sites or unapproved posts. In the event of employee turnover, there is a risk of losing the account passwords.

Management of the Risk – Life sciences manufacturers should have proper password protections in place and create redundancy for key system access information to an internal independent authority (i.e., internal Information Technology personnel) and establish a process for the transfer of security information in the event of personnel turnover. Manufacturers should have processes in place to record and archive their social media activities, including posts, comments, and interactions.

It is crucial for manufacturers to stay updated on the evolving regulatory landscape and engage with IT, legal, and compliance teams to ensure that their social media activities align with the applicable regulations in their respective regions.



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