Best Practices as a Legal Reviewer for Promotional Review Committees

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Background

A Promotional Review Committee (PRC) is comprised of a group of individuals tasked with reviewing and approving regulated content intended to be used in advertising and promotion. Generally, in the pharmaceutical, biotech, and medical device industries, there are representatives from Commercial/Marketing, Medical, Regulatory, and Legal on the PRC to help ensure that content meets the objectives of each of those departments. This article will explore overall best practices to encourage collaboration, reduce conflict, and efficiently further commercial success.

The legal reviewer is charged with reviewing materials with consideration of all relevant U.S. federal, state, and local laws, rules, regulations, industry standards, and relevant company policies. A legal reviewer, among other things, is responsible for reviewing materials to help ensure that they are consistent with the full Prescribing Information or Instructions for Use (on-label) and to identify issues that may raise legal concerns such as false or misleading claims or content, product liability, anti-trust considerations, lack of fair balance, and inappropriate comparative or superiority claims. The legal reviewer helps ensure that the presentation of information is in the appropriate context, that trademarks, copyrights, and other intellectual property are appropriately used, and that other highly regulated activities and communications, including those related to product reimbursement, patient assistance programs, and patient engagement and consumer outreach are carefully considered.

Best Practices for Consideration

- Clearly define roles and responsibilities: When roles are clearly defined, each department involved in the PRC process knows exactly what they're responsible for. This will help departments appreciate the role each individual plays and maximize the collaboration component, and value that each individual can provide. Additionally, finding the right balance and ensuring members are able to provide their feedback will create an environment where individuals can have open discussions. Companies are encouraged to have policies or guidelines defining roles and responsibilities and associated training so that the PRC can be more efficient.

- Seeing things from the other's perspective: Marketing is tasked with developing ideas that promote a product, medical device, or disease state. At the same time, Marketing should understand the roles of Regulatory, Legal, and Medical and help facilitate the review process by making sure materials are on-label, consistently and fairly represent the studies and data within the label, are fairly balanced, and are scientifically accurate based on the label and references cited. Each department should understand that they are working towards the shared goal of compliantly promoting a product, medical device, or disease.

- Finding common ground: It's important to pick and choose your battles! Try to find common ground and develop alternative suggestions to resolve issues instead of just saying “no.” Being specific and more direct with your messaging will help reduce any miscommunication and advance materials along the PRC process.

- Use PRC meetings strategically: Prioritize issues that make live meetings more focused, productive, and efficient. If possible, provide comments and revisions in advance of the live meeting so that reviewers are aware of each other's feedback and can opine if necessary.
- Include stakeholders for additional expertise: If you reach an impasse, you may want to include stakeholders where necessary to get additional expertise. A company may want to involve stakeholders from compliance or pharmacovigilance, or senior leadership to identify potential risks to the company.

Takeaway

As the Office of Prescription Drug Promotion (OPDP) continues its focus on promotional activities, a company's PRC or review process in general is key for compliant company activities. Companies are encouraged to maintain policies or procedures regarding the PRC process to promote compliance with laws and regulations and collaboration among the departments. If you have any questions concerning the material discussed in this client alert, please contact the members of our Life Sciences team.