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Background

Currently, there are many channels available to promote pharmaceutical products to consumers and healthcare professionals. Promotional materials are under increased scrutiny to remain in compliance with industry guidance and regulations. The Food and Drug Administration's Division of Drug Marketing, Advertising, and Communication (DDMAC) sent out 41 enforcement letters in 2009 compared to 21 letters in 2008. As of January 2010, the agency sent out 8 enforcement letters versus only 2 letters in January 2009.¹ Materials may be cited for numerous violations, including omission / minimization of risk information, overstatement of efficacy, and broadening of indication.

The medical review of promotional materials is routinely a responsibility of the Medical Information Department, and is essential to uphold scientific and medical accuracy, fair-balance, and evidence-based claims. However, there is a lack of information regarding the Medical Information representative's current role and involvement in promotional review.

Objective

To assess the Medical Information Department's current function and level of involvement in the review and evaluation of promotional materials.

Methodology

Design

A 34 question, internet-based survey was distributed via SurveyMonkey to 34 Medical Information representatives from 19 different pharmaceutical and biopharmaceutical companies. The survey was designed to identify the respondent's personal experience in promotional review in regards to timing, procedure, and type of materials. Of the 34 questions, 24 were multiple choice, 7 were ranking, and 3 were open-ended. Due to the nature and context of some multiple choice questions, 6 were "check all that apply" and 9 provided an option for additional comments. All responses were kept anonymous.

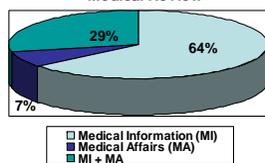
Evaluation of Survey Respondents

- Of the 34 Medical Information representatives contacted, 50% responded to the survey (N=17).
 - 71% (n=12) completed the entire survey.
 - 29% (n=5) did not complete every question.
 - Information provided from these respondents were included in analysis.
- All respondents were directly involved in the legal-medical-regulatory review of promotional materials.
- Majority of survey respondents (n=13) have a Pharm.D. degree.

Results

Medical Information Department in Promotional Review

Department Responsible for Medical Review



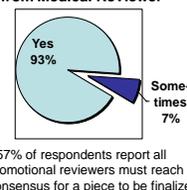
Training

- 92% of respondents reported receiving training prior to assuming the responsibility of medical reviewer

Back-up Medical Reviewer

- 21% of medical reviewers do not have a back-up reviewer when they are unavailable
- Majority (72%) report Medical Information and/or Medical Affairs departments are responsible for back-up, while 7% report Legal department is responsible

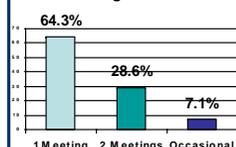
Formal Approval Required from Medical Reviewer



- 57% of respondents report all promotional reviewers must reach a consensus for a piece to be finalized

Formal Promotional Review Meetings

Meetings Per Week

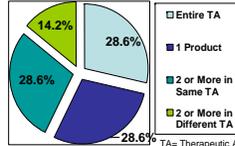


Products Reviewed / Time in Meetings

- 64% of respondents review one product per formal meeting, 29% review all products in therapeutic area at each meeting
- > 50% of respondents spend 5 hours or more in formal promotional review meetings per week

Products / Materials Supported

Products Medical Representative Reviews

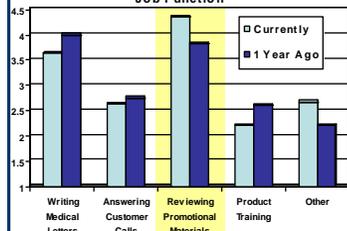


Promotional Materials

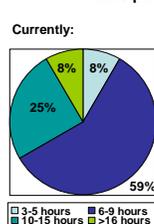
- Promotional materials reviewed per month:
 - median 35 [range: 4-70]
- 100% of respondents review slide decks, print ads, patient brochures, sales aids, and training bulletins

Time Spent Reviewing Promotional Materials

Average Ranking Least (1) to Most (5) Time per Job Function



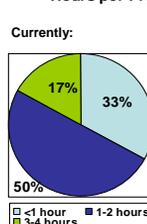
Hours per Week



Compared to One Year Ago:

- 58% report this is an increase from one year ago
- 42% report it is the same as one year ago

Hours per Promotional Piece



Compared to One Year Ago:

- 50% report this is an increase from one year ago
- 50% report it is the same as one year ago

Discussion

- The Medical Information representative dedicates an extensive amount of time to the medical review of promotional materials.
 - 84% of respondents spend between 6-15 hours per week reviewing promotional materials plus >50% spend 5 hours or more in formal promotional review meetings per week.
- Promotional review was ranked the most time consuming job function currently, an increase compared to one year ago. The more traditional Medical Information job functions were rated to be less time consuming compared to last year. This may represent a shift in focus of the Medical Information Department.
- Reasons for the increase in time being spent on promotional review compared to one year ago cannot be determined from this survey, but may include the increase in regulatory scrutiny, number of products, or decrease in resources.
- The burden of this large time commitment may create new challenges for Medical Information Departments. Structural and/or procedural changes may need to be addressed by department supervisors.
- Further evaluation should be conducted on the extent of training prior to assuming the role of medical reviewer. Appropriate training will enhance the quality of review and time management.

Limitations

- Small sample size (N=17) makes it difficult to generalize promotional review findings to all Medical Information Departments.
- Survey questions were not validated.
- Surveys were sent to 1 or 2 employees per company.
 - Results may not equally represent all companies.
- Quantitative data may be based on respondent's recall and not predefined metrics.
- Promotional activity and volume differs across products / therapeutic areas, which will reflect in different experiences across respondents.

Conclusions

- Overall, the Medical Information Department is responsible for medical review of promotional materials. This responsibility is shared with Medical Affairs (MDs) in some companies.
- Promotional review requires a substantial amount of time from the Medical Information representative, and is currently rated their most time consuming job function.
- The amount of time being spent on promotional review has increased compared to last year, and this may create new challenges for the Medical Information Department.

References

¹ Warning Letters and Notice of Violation Letters to Pharmaceutical Companies. Food and Drug Administration Web site. Available at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/Warning_lettersandNoticesofViolationLetterstoPharmaceuticalCompanies/default.htm. Accessed 15 February 2010.