Background

FDA’s Division of Drug Marketing, Advertising, and Communications (DDMAC) regulates the promotional activities of pharmaceutical manufacturers in the United States. DDMAC evaluates DTC promotions to ensure regulatory letters (published literature) and Warning Letters (issued by DDMAC) and Warning Letters are likely an important influence on these promotional review practices. Industry promotion reviewers may interpret these letters as indicators of DDMAC priorities, and/or as guidelines for promotion content. The nature and extent of the influence of DDMAC letters or promotion review practice, to our knowledge, has not been examined in the published literature.

Objectives

- To characterize the relationship between DDMAC letters and promotional review practices in the pharmaceutical industry.
- To evaluate the content of DDMAC Violation Letters for patterns of enforcement with regard to violation types, drug categories, and types of promotional materials.

Methodology

- A web-based, anonymous survey consisting of 37 questions investigating the impact of DDMAC letters on promotional review was developed and administered. Non-respondents to the pharmaceutical and/or promotional companies. The survey was designed to quantify the impact of DDMAC letters on promotional review decisions, versus other influences, and assess for perceptions of DDMAC enforcement activities, with regard to a variety of particular violation types, drug classes, and promotional material types.
- DDMAC regulatory letters from years 1997-2009 were evaluated online by the FDA, were assessed and evaluated
- Information included included cited violation types, types of promotional materials referenced, and category of drug product affected the violationable promotional activities mentioned in the letters were per the FDA and Comparisons categorized.

Results

- Table 1: Survey Respondent Demographics

<table>
<thead>
<tr>
<th>Company Function*</th>
<th>n (% of respondents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marketing</td>
<td>38 (71)</td>
</tr>
<tr>
<td>Medical Communications</td>
<td>25 (46)</td>
</tr>
<tr>
<td>Regulatory Affairs</td>
<td>16 (30)</td>
</tr>
</tbody>
</table>

- Graduate Degree*:

<table>
<thead>
<tr>
<th>Degree</th>
<th>n (% of respondents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>JD</td>
<td>1 (0.1)</td>
</tr>
<tr>
<td>MBA</td>
<td>3 (5.8)</td>
</tr>
<tr>
<td>MS</td>
<td>3 (6.3)</td>
</tr>
<tr>
<td>PhD</td>
<td>11 (21.1)</td>
</tr>
</tbody>
</table>

- Years of Promotional Review Experience*:

<table>
<thead>
<tr>
<th>Experience</th>
<th>n (% of respondents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-1</td>
<td>85 (71.9)</td>
</tr>
<tr>
<td>1-2</td>
<td>25 (21.1)</td>
</tr>
<tr>
<td>2-3</td>
<td>4 (3.3)</td>
</tr>
<tr>
<td>3+</td>
<td>2 (1.7)</td>
</tr>
</tbody>
</table>

Discussion

- Other have discussed the importance of DDMAC letters in instructing marketing efforts. Survey respondents in our study agreed that, generally, those letters were as important, if not more important, than other influences in the promotional review process.
- Some respondents felt that DDMAC violation letters were more important to consider than others, whereas others felt that certain promotional activities were more closely scrutinized than others.
- Indicates how promotional review respondents feel DDMAC does not uniformly regulate all promotional activities. Given the finite resources and relative small staff of DDMAC, not only is the agency likely to direct and pursue its more aggressive practices.
- Overall decrease in regulatory activities from 1997-2004, and a noteworthy stable quantity 2004-2009, a significant increase in violation letters was issued in 2009, despite years DDMAC submissions increase from 1997-2004.
- May reflect increased industry compliance in changes in DDMAC resources, staff, direction. Reduced letter output after 2002 had been attributed to policy change limiting enforcement for letter release by DDMAC. Further study is needed to evaluate these and other potential factors.

- Limitations

- Survey respondents were small, heterogeneous cohort
- Difficult to generalize survey findings to all pharmaceutical professionals, or the industry as a whole.
- Survey respondents indicated (data not shown) that important factors affecting promotional review, such as company policies on pr, views and DTC/other agreements with government agencies were not uniform across the respondent companies.
- These factors may have confounded perspectives on influence of strategies, such as education/employees, comments.
- Letter analysis results were limited to publicly available violation letters.
- Letter analysis results were limited to the operational definitions used in the study to categorize information from the violation letters.

Conclusions

- Survey respondents on average rated DDMAC violation letters at least as important as other categories of influence on pr review practices.
- DDMAC violation letters to respondents' companies were rated as most important, with an overall 20.7% of resource points allocated to this category.
- While most respondents (74%) did not feel certain violation types were more important to consider in promotional review, or that certain drug categories were more closely scrutinized by DDMAC, respondents (9.7%) did feel certain promotional material types were more closely reviewed.
- While DTC print and broadcast promotions were a relatively small percentage of promotional activities mentioned in DDMAC violation letters (2% in 2009, 13% 1997-2009), this is not necessarily an indicator of DDMAC surveillance or enforcement activity with these material types.
- Most respondents reviewed and participated in issues regarding DTC issues (over 97%).
- Respondents rated DDMAC Warning and Untitled Letters as important as, or more important than, other influences.
- Mean % of resource points allocated (n=17 respondents)

- Table 2: Selected Survey Results

- Figure 1: Rating the Importance of Prom. Review Influences

- Figure 2: Perceptions of DDMAC enforcement

- Figure 3: Rating DDMAC Scrutiny of Promotional Material Types

- Figure 4: Warning and Untitled Letters 1997-2009

- Figure 5: Selected Violation Categories

- Figure 6: Selected Violation Categories

- Figure 7: Promotional Material Types

References


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