Current Practices in the Pharmaceutical Industry for the Dissemination of Post-Marketing Drug Safety Information

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Background

Pharmaceutical and biotechnology manufacturers actively collect and analyze all available safety information on their products. However, pharmaceutical manufacturers' internal safety information was found to be used least often when responding to drug safety inquiries from external customers.[1] Furthermore, one Food and Drug Administration (FDA) analysis showed that the "ascertainment of adverse events [from drug manufacturers] was highly variable and sometimes incomplete."[2] In an environment where both the FDA and manufacturers are under increased scrutiny from the public eye, it is important to maintain consistency in the amount and type of drug safety information provided to customers.

Objective

To evaluate the practice patterns within Medical Communications departments for disseminating post-marketing drug safety information, including unpublished information, in response to medical information (MI) inquiries from health care professionals (HCPs) and consumers.

Methodology

- In December 2008, a 20-question, multiple-choice, online survey was sent via electronic mail (email) to 31 pharmaceutical and biotechnology companies across the U.S. in which medical information (MI) and/or medical affairs (MA) personnel contact was available
- Recipients were given seven days to complete the survey with one reminder sent via email 24 hours prior to completion deadline
- Initially, all respondents answered four general demographic questions. Following that, two primary branching questions were used to identify the scope of drug safety information disseminated to health care professionals (HCPs) and consumers
- Depending on the response to the primary branching questions, respondents continued the survey to answer 10 questions specific to what sources of additional information are used to respond to HCP and consumer drug safety inquiries, how the information is generated, what information is included in the response, and which department(s) are responsible for the review and dissemination of the response
- The final four questions pertained to formalized, internal company processes surrounding the dissemination of unpublished, post-marketing drug safety information to external and internal customers. All respondents answered these four questions
- Recipients were informed that the results would remain anonymous and were to be analyzed in aggregate; respondents received the results if they provided their email address at the end of the survey

Demographics

- Of the 31 companies surveyed:
  - 7 (22%) completed the survey
  - 7 (22%) partially completed the survey (included in the results)
  - 17 (56%) failed to respond to the survey
- 93% (13/14) of responses were received from medium to large pharmaceutical companies (> 2,500 employees[3])
- 77% (10/13) of companies receive over 100 adverse event (AE) medical information inquiries per quarter
  - The amount of AE inquiries received per quarter that are specific to post-marketing AE information are presented in Figure 1. Quantity of Adverse Event Medical Information Inquiries Specific to Post-Marketing Adverse Events Received by Companies Quarterly (n=13)

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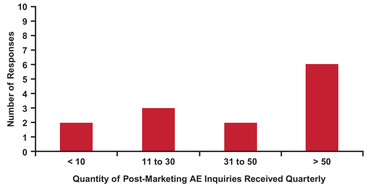
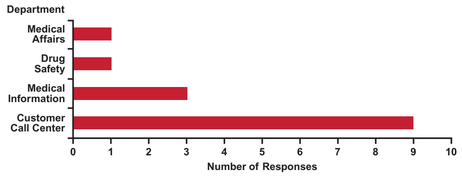
Figure 1 – Quantity of Adverse Event Medical Information Inquiries Specific to Post-Marketing Adverse Events Received by Companies Quarterly (n = 13)



- Of the 14 companies that responded:
  - 1 reported that their department supports < 5 products
  - 10 reported that their department supports 5 to 25 products
  - 2 reported that their department supports 26 to 50 products
  - 1 reported that their department supports > 50 products
- Respondents reported that the Customer Call Center receives the majority of initial AE reports and/or general AE inquiries (see Figure 2)

Figure 2 – Department that Receives the Majority of Initial Adverse Event Reports and/or General Adverse Event Inquiries (n = 14)



Results

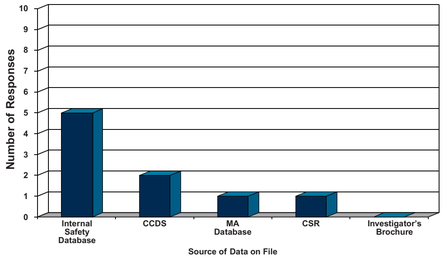
- No companies provide additional information to consumers who inquire about post-marketing adverse events other than information already contained in the U.S. Prescribing Information or Patient Medication Guides
- The sources of information used by companies when responding to health care professional (HCP) inquiries regarding post-marketing AEs are presented in Table 1 and Figure 3
- Overall, one company reported that they disclose the clinically relevant case details to HCPs when asked about post-marketing AEs (n = 7)

Table 1 – Sources of Information Used to Respond to Health Care Professional Inquiries Regarding Post-Marketing Adverse Events*

Source of Information	Number of Responses
U.S. Prescribing Information	14
Published Literature	14
Data on File	6†
Other	0

*Respondents (n=14) could "Check all that apply"
†See Figure 3

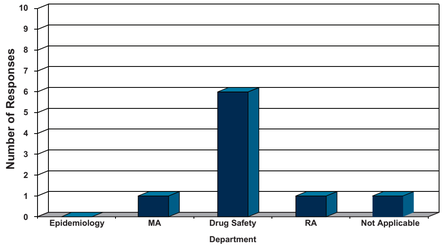
Figure 3 – Sources of Data on File Used to Respond to Health Care Professional Inquiries Regarding Post-Marketing Adverse Events*



*Respondents (n=6) could "Check all that apply"
CCDS = Company Core Data Sheet; MA = Medical Affairs; CSR = Clinical Study Report

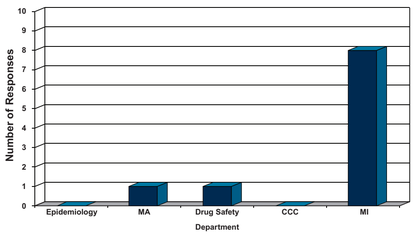
- 71% (10/14) companies have a formalized, internal process describing how unpublished, post-marketing safety information is generated from internal database(s) and disseminated to external customers
  - The Drug Safety and Medical Information (MI) departments were primarily responsible for compiling and writing responses, respectively, that contain unpublished, post-marketing AE information (see Figure 4 and 5)
  - Seven companies have a review process for the information generated from the analyses that is performed prior to dissemination to external customers (see Figure 6)
  - When disseminating unpublished, post-marketing safety information from internal resources to external customers, two and three companies preferred to use only written and verbal communication, respectively, while six had no preference

Figure 4 – Partnering Departments for Compiling Unpublished, Post-Marketing Adverse Event Information in Response to Health Care Professional Requests*



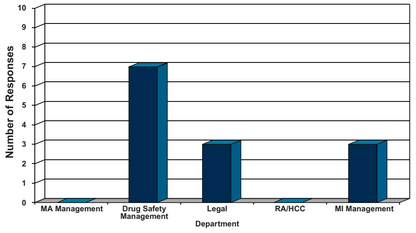
*Respondents (n=7) could "Check all that apply"
MA = Medical Affairs; RA = Regulatory Affairs; Not Applicable = "Drug information has access to this information"

Figure 5 – Departments Responsible for Writing Responses Containing Unpublished, Post-Marketing Adverse Event Information for Health Care Professional Requests*



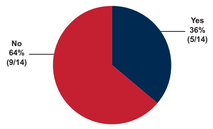
*Respondents (n=7) could "Check all that apply"
MA = Medical Affairs; CCC = Customer Call Center; MI = Medical Information

Figure 6 – Departments Responsible for Reviewing Unpublished, Post-Marketing Safety Analyses Generated from Internal Safety Databases Prior to Dissemination to External Customers*



*Respondent (n=9) could "Check all that apply"
MA = Medical Affairs; RA = Regulatory Affairs; HCC = Health Care Compliance;
MI = Medical Information

Figure 7 – Proportion of Companies that Disseminate Unpublished, Post-Marketing Safety Analyses from Internal Safety Databases to Select Internal Business Partners (U.S. and ex-U.S.) on a Routine Basis (n = 14)



- All companies who routinely disseminate safety information analyses from internal safety databases do so on a quarterly basis
- These analyses are disseminated internally through email (n = 2), meetings/teleconferences (n = 3), and through inclusion in the product-specific Company Core Data Sheet (n = 2)

Discussion

- No correlations between various demographic information gathered and company processes surrounding the dissemination of safety information, including unpublished, post-marketing adverse event (AE) information, were identified.
- While about half of the companies surveyed disseminate additional internal company data (that is, Data on File) other than the information already contained in the USPI or published literature to HCPs requesting information about post-marketing AEs, no companies will provide Data on File to consumers with similar requests. The most common source of Data on File to provide HCP's is generated from companies' internal safety database(s).
- Once a request regarding unpublished, post-marketing AE information is received by the MI department, they partner with the Drug Safety department to compile data for the response. The MI department then drafts the response and Drug Safety Management reviews this. Finally, the response is disseminated to HCPs through either verbal or written communication and typically report whether or not the event has occurred since approval. Clinically relevant case details surrounding unpublished, post-marketing adverse events are rarely disseminated to HCPs upon request.
- Generally speaking, the majority of companies do not routinely disseminate internal safety database analyses to key internal business partners.

Limitations

- Lack of variation in the demographics of respondents
- Half (7/14) of the responses were partial but were included in the analysis
- Two responses were received from the same company; the first response received was included in the analysis, the second was discarded as the response was identical to the first

Conclusion

The only consistent factor common to all respondents is that they will refer to publicly available information (that is, USPI, published literature) for each inquiry received pertaining to post-marketing AEs. The results of this study indicate that there are no standardized practices throughout the Pharmaceutical Industry regarding the dissemination of unpublished, post-marketing adverse event data to health care professionals. However, this study did determine that, in the event that this information is provided, it would be generated from a companies' internal safety database through a pre-specified, formal process involving both the Medical Information and Drug Safety departments.

Acknowledgments

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References

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