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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 restricted and thus unreachable by external customers, particularly when safety data were generated by the FDA and not disseminated to external customers (e.g., prescribers and patients). The Food and Drug Administration (FDA) guidelines acknowledge the “adverse event of drug safety” and vary in terms of what constitutes adverse events. In an environment where both the FDA and manufacturers are under increased scrutiny from the public, 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 safety information, including what constitutes adverse events, in response to medical information requests from health care professionals (HCPs) and consumers.

METHODOLOGY
In December 2008, a 25-question, multiple choice, online survey was conducted via Survey Monkey® (www.surveymonkey.com) and administered to respondents of Medical Communications departments across the U.S., in which medical information (HCP) or pharmaceutical sales (HRA) personal contact was available.

Recipients were given seven days to complete the survey with no reminder sent to email 24 hours prior to closing deadline.

Initially, all respondents answered four general demographic questions. Following this, two primary branching questions were used to provide the scope of the survey and to determine the amount of drug safety information disseminated to health care professionals (HCP) and consumers.

Depending on the response to the primary branching questions, respondents continued to answer 11 questions pertaining to what sources of additional information are used to respond to HCP and consumer drug safety information queries, how the information is generated, and what constitutes adverse events. The survey concluded with questions for the respondent’s job role, department, and company demographics.

The final four questions pertained to formalized, internal company processes surrounding the dissemination of post-marketing drug safety information to external and internal customers. All respondents answered all questions.

RESULTS
Of the 41 companies that responded:
- 1 reported that their department supports >50 products
- 3 reported that their department supports 31 to 50 products
- 2 reported that their department supports 25 to 30 products
- 10 reported that their department supports 10 to 20 products
- 9 reported that their department supports 5 to 19 products
- 10 reported that their department supports ≤5 products

Respondents reported that the Customer Call Center receives the majority of initial adverse event inquiries. However, the three companies that reported that the Medical Information department received a significant proportion of initial adverse event inquiries also noted that the primary role for handling these inquiries is performed by the Customer Call Center. The companies that reported that the Customer Call Center received the majority of initial adverse event inquiries also noted that the Medical Information department is responsible for compiling and writing responses, respectively, that contain adverse event information.

Seven companies have a process for the information generated from the analysis of adverse event reports that is performed prior to dissemination to external customers (see Figure 6).

When analyzing the unpublished, post-marketing safety information from the company’s safety database, companies are required to write only written and verbal communication, respectively, which is not required of the Memorial Sloan Kettering Cancer Center for dissemination to external customers.

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

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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)

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

Figure 3 – Sources of Data in Files Used to Respond to Health Care Professional Inquiries Regarding Post-Marketing Adverse Events

Figure 4 – Partnering Departments for Compiling Unpublished, Post-Marketing Safety Analyses in Response to Health Care Professional Requests

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

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

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)

DISCUSSION
No conclusions between specific demographic information (e.g., company size) and responses was found. The only consistent factor common to all respondents is that they will refer to publicly available information (that is, U.S. Pharmacopeia, published literature) for each inquiry. Specifically, five out of six companies (9/14) who routinely disseminate safety information analyses from internal safety databases to select internal business partners noted 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 a consistent response list would be generated from a consultant, a response list that includes the following would most likely include the disseminated drug safety and Drug Safety departments.

LIMITATIONS
The only consistent factor common to all respondents is that they will refer to publicly available information (that is, U.S. Pharmacopeia, published literature) for each inquiry. Specifically, five out of six companies (9/14) who routinely disseminate safety information analyses from internal safety databases to select internal business partners noted 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 a consistent response list would be generated from a consultant, a response list that includes the following would most likely include the disseminated drug safety and Drug Safety departments.

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REFERENCES