# Analysis of Medical Information Standard Response Structure across Pharmaceutical Companies

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## Background

- Pharmaceutical companies commonly provide medical information to healthcare provider inquiries through written standard response letters.
- The US Food and Drug Administration provides some guidance on standards for responding to unsolicited requests.[1]
- The FDA Draft Guidance provides the following standards: information distributed in response to an unsolicited request should be provided only to the individual making the request; the information should be tailored to answer only the specific question; information should be truthful, non-misleading, accurate, and balanced; information should be scientific and generated by medical or scientific personnel; and specific information needs to accompany the distribution of the unsolicited request.[1]
- The Draft Guidance is not very clear on the specifics of these requirements and how standard responses can be structured to account for all of these factors.[1]

## Objective

- To identify how pharmaceutical companies structure their medical information standard responses to communicate relevant information to healthcare providers.
- This data can be used to develop best practices of how information is effectively communicated to healthcare providers and create clarity on how select pharmaceutical companies provide answers to healthcare providers focusing on the structure of the responses.

## Methods

- This research was reviewed by the Rutgers Institutional Review Board.
- This was an open-label, prospective, anonymous survey.
- The survey contained 10 questions.
- The survey was distributed to 25 pharmaceutical companies through an online survey tool.
- Some factors evaluated and answered through the survey include:
  - Location of the answer (immediately on the cover page or in the body of the standard response)
  - Length of standard response (1-2 pages, 3-5 pages, 5-10 pages, > 10 pages)
  - Inclusion of prominent safety information (direct lift from the prescribing information, reference to the prescribing information, inclusion of a hyperlink)
  - Inclusion of approved product indications (direct lift from the prescribing information, reference to the prescribing information, inclusion of a hyperlink).

## Results

- Of the 25 pharmaceutical companies surveyed, responses were received from 12 companies
- Based on survey results, the answer to the inquiry can be found predominantly in the standard response (83%) vs. the cover page (17%), **Figure 1.**
- On average, the length of standard responses varied with the majority between 1 – 2 pages (42%) and 3 – 5 pages (42%), **Figure 2.**
- 11 of the pharmaceutical companies surveyed provide cover letters with the standard response.
- Within the cover letter, there are various relevant sections contained, **Figure 3**:
  - Product indications (58%), boxed warning (42%), important safety information and warnings (50%), and prescribing information hyperlink (33%).
- Safety information in a standard response can be found predominantly as a direct lift in the standard response (33%) or a direct lift on the cover page (17%), **Figure 4.**
- Approved indications in a standard response can be found as a direct lift on the cover page (42%) , direct lift in the standard response (25%), or not provided (17%), **Figure 5.**

**Figure 1. Location of the Answer in the Standard Response Package**

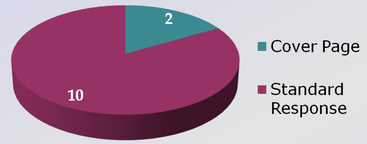



**Figure 2. Average Length of Standard Response to a Single Inquiry**

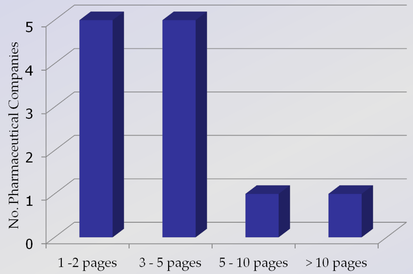



**Figure 3. Relevant Sections Contained in the Cover Letter**

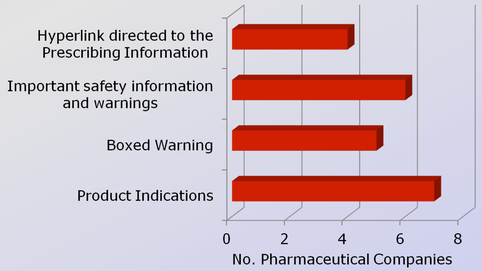



**Figure 4. Location of Safety Information in a Standard Response**

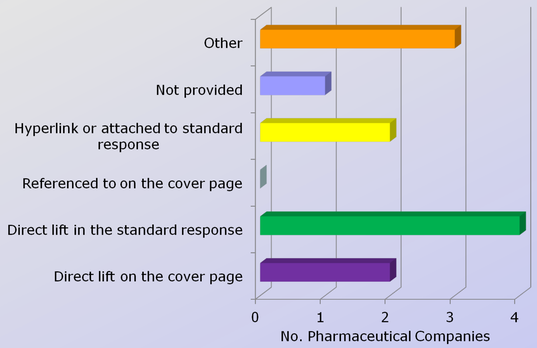
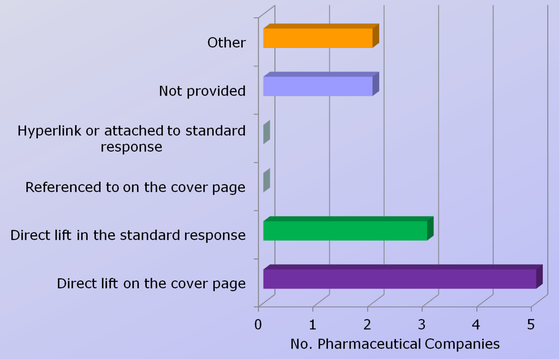



**Figure 5. Location of Approved Indications in a Standard Response**




## Discussion

- Of the 25 pharmaceutical companies surveyed, 12 responses were received.
- The results of the survey varied across the 12 pharmaceutical companies that responded.
- Among the companies surveyed, the answer to the inquiry can be found predominantly in the standard response (83%) vs. the cover page (17%).
- On average, the length of standard responses to a single inquiry fall less than 4 pages, for the majority of companies surveyed.
- Furthermore, the location of the safety information and product indications are found mainly as a direct lift on either the cover page or directly in the standard response.

## Limitations

- A limitation of this study included the number of pharmaceutical companies sampled. A greater sample of pharmaceutical companies could have been surveyed to achieve a more diverse sample.
- An additional limitation of this study included the subjectivity of the questions included in the survey.

## Conclusions

- Results of the survey indicate there is no consistent structure of medical information standard responses utilized across pharmaceutical companies. However, there are some commonalities including maintaining the standard response to < 5 pages thus providing a concise response to consumer inquiries.
- The implications of the results is to begin establishing more clear guidance around a consistent medical information standard response structure that aims to be scientific, accurate, fair, and balanced, ultimately, meeting the needs of the customer.

## References

1. Food and Drug Administration. Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices. Updated: December 2011. Available at: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm285145.pdf. Accessed 20 February 2015.

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- The authors have nothing to disclose.

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