Why Life Sciences Companies Should Engage on Social Media

Impact of FDA guidance on social media strategies for life sciences companies

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Today, while most industries are rapidly taking up Social Media to listen to and engage with customers, the Life Sciences industry has remained cautious in its social endeavors. Owing to the lack of clarity on social media guidelines Life Sciences companies balk at extending social presence in a highly regulated environment.

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Life Sciences companies considering an entry into the social media space have naturally been wary about discussion of adverse events. Are consumers sharing information online that would indicate an adverse experience? Does monitoring the social media trigger the Adverse Event reporting requirement? Would Life Sciences companies be drowned in a deluge of Adverse Events on social media?

In the view of these FDA guidelines, this white paper aims to shed light on the realities of Adverse Event Reporting in social media. Bolstered with meaningful research and numbers, this paper intends to assist Life Sciences companies in determining the scope and potential impact of creating a social media engagement program.

Abstract

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In the view of these FDA guidelines, this white paper aims to shed light on the realities of Adverse Event Reporting in social media. Bolstered with meaningful research and numbers, this paper intends to assist Life Sciences companies in determining the scope and potential impact of creating a social media engagement program.
Life Sciences Companies – Shying Away from Social Media

The Life Sciences industry is hugely competitive and highly regulated. Pharma companies today are fairly wary in their approach to social media, mainly because of the lack of clarity on regulations for social media laid down by the US Food and Drug Administration (FDA).

According to guidelines, when a Life Sciences company has knowledge of any adverse event, it has an obligation to file a report with the FDA through the Form 3500A-Mandatory Reporting.

An adverse event (AE) is defined as any unfavorable and unintended sign including abnormal laboratory finding, symptom or disease associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure.

Considering the nature of social media Life Sciences companies are concerned about consumer discussions that would indicate an adverse experience. Due to the lack of guidance it is not clear if monitoring these discussions would trigger the AE reporting requirement. At this time, there is no FDA guideline or regulation that specifically covers the content of online discussion in a way that is different from reporting AE information derived from any other source.

Current FDA guidelines give four parameters for submitting information about adverse experiences. These include: an identifiable patient, an identifiable reporter, a specific drug or biologic involved in the event, and an adverse event or fatal outcome.

According to the guideline: “If any of these basic elements remain unknown after being actively sought by the applicant, manufacturer, or licensed manufacturer, a report on the incident should not be submitted to the FDA because reports without such information make interpretation of their significance difficult, at best, and impossible, in most instances”.

To make a case for Life Science companies to listen on the social media, we need to look at two key questions:

1. When adverse experiences are mentioned within consumer-generated media, do they meet the FDA’s criteria for reporting?

2. If Pharma companies are monitoring the social media, are they obligated to respond to any unsolicited requests on such consumer-generated media?

To answer the first question I did an analysis of 2100 messages related to Pharma and Medical Device products posted online across various internet forums.

Methodology

The research was carried over 9 prescription drugs (Hydrocodone, Amoxicillin, Lipitor, Lisinopril, Simvastatin, Plavix, Nexium, Singular, Lexapro) and 4 medical devices (Medtronic’s Revel, Resolute and Paradigm, Moog’s Curlin). These 13 brands were monitored on online forums such as Twitter, Facebook, Reddit, Delicious, Digg, Medscape, Blogs, etc. for a period of 7 days using a social listening platform and the results were examined. Youtube results were omitted in this research.

This social monitoring was performed using Wipro’s Social Media monitoring platform. This platform searches user-generated content such as blogs, comments, bookmarks, events, news, and videos across the social media space directly.

The table below shows the number of messages that were analyzed for each drug/device.

<table>
<thead>
<tr>
<th>Drug/Device</th>
<th>Total Messages</th>
<th>Relevant Messages</th>
<th>AE Mention</th>
<th>AER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocodone</td>
<td>195</td>
<td>10</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>210</td>
<td>10</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Lipitor</td>
<td>210</td>
<td>10</td>
<td>7</td>
<td></td>
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<tr>
<td>Lisinopril</td>
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<td>10</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>150</td>
<td>10</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Plavix</td>
<td>150</td>
<td>14</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>Nexium</td>
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<td>1</td>
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<tr>
<td>Lexapro</td>
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<td>Resolute</td>
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<td>Paradigm</td>
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<td>Moog Curlin</td>
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<td>4</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>2100</td>
<td>101</td>
<td>62</td>
<td>8</td>
</tr>
</tbody>
</table>

Key Findings

The research revealed that for all posts containing mentions of the 13 brands considered for this study:

- Only 3% of all posts have mention of an Adverse Reaction
- Only 0.38% messages actually qualify for an Adverse Event Reporting
- The incidence of Adverse Events is almost same for Pharma Drugs and Medical Devices
- The messages with mention of Adverse Events are however considerably less for Medical Devices as compared to Pharma Drugs.
The figures in this research suggest that a Life Sciences company that aggressively monitors social media may pick up the occasional AE within patient or physician online discussion. However an instance qualifying for Adverse Event Reporting would be encountered very rarely, with a volume that would be entirely manageable within the company’s broader AE monitoring programs.

**FDA Guidance**

To answer the second question, i.e. whether Life Sciences companies that are monitoring social media, are obligated to respond to any unsolicited requests on such consumer-generated media, we analyze the FDA draft guidance addressing how Pharmaceutical and Medical Devices companies may respond to unsolicited requests for off-label information.

Off-label use is the practice of prescribing pharmaceuticals for an unapproved indication or in an unapproved age group, unapproved dose or unapproved form of administration.

The FDA issued draft guidance on Dec. 27, 2011. The guidance addresses how manufacturers should respond to non-public and public requests for off-label information. This guidance for responding to questions posed in public online forums what the FDA calls “emerging electronic media” directly addresses forums such as Twitter, YouTube and discussion boards for first time. Two key points of relevance for the Life Sciences companies are:

1. The company has the choice to respond to unsolicited requests or not.
2. If the company chooses to respond, the actual response can only be provided in a private, one-on-one communication. This applies to questions posed in both a private and public setting.

Though not directly addressing Adverse Event reporting; the guidance does provide some insight into FDA’s stance on Social Media.

**The Course of Action for Life Sciences Companies**

From the research it is clear that an overwhelming majority of posts on social media do not meet the FDA criteria for adverse events. In this research only 0.38% of the monitored posts qualified for Adverse Event reporting. However the benefits of social listening far outweigh the risks. The companies that actively engage in social listening can:

1. Understand patients’ doubts and concerns - patients, who are new to a treatment often have doubts about when and how to take it.
2. Avert risk of unapproved usage - Monitoring and immediately responding to off-label use, and any related conversations can avert the risk of unapproved usage.
3. Learn about patients’ experiences using the product - Candid feedback through online queries such as: Is the packaging difficult to open? Is the dropper too short? What are the concerns while using the medical device? Can significantly help in improving product characteristics.
4. Conduct competitive analysis – In open social forums it is easier for companies to understand what patients and physicians are discussing about competitive products. Which attributes are more valued and which attributes are pain areas. They can also determine how their product is perceived against other products in the similar category.
5. Engage with caregivers – Increasing number of caregivers are participating in online discussions. A recent survey by Google & Manhattan Research found that 93% of physicians influence treatment decisions based on online clinical & treatment information. This presents a huge opportunity to equip caregivers with the right and complete information about your product.

Life Sciences companies need to develop their social strategy and employ tools and platforms for social listening and managing social media communication. The social strategy should incorporate people, process and technology.

**People:** Life sciences companies would need social media consultants who understand the social space and the life sciences domain and can integrate it with their marketing strategy.

**Process:** Business processes need to be established to ensure that all communication follows an approval process and is communicated to the appropriate stakeholders and compliant with OPDP (Office of Prescription Drug Promotion) regulations.

**Technology:** For a single view of social media across business units and geographies companies may implement a digital marketing platform that would aggregate data from various sources, implement business processes, help in campaign management and provide analytics & reporting for gaining actionable insights.

The future of Life Sciences marketing is in being part of the conversations in the online space.
Conclusion

The FDA guidance on the responsibilities of Life Sciences companies monitoring the social media comes as a sigh of relief. The concerns regarding a deluge of Adverse Event reporting can be set aside as the comments that qualify as Adverse Events are miniscule and online presence doesn’t add to the obligations of the Life Sciences Company.

The benefits of social listening far outweigh the concerns that companies share. So it makes business sense for Life Sciences companies to extend their online presence and listen to and engage with patients and physicians on social media.
References


3. Neilsen’s research on Listening to Consumers in a Highly Regulated Environment.


4. intouchsol’s analysis of the FDA guidance on response to unsolicited response to off label-info.


5. Visible’s research on Adverse Event Reporting in Social Media.

    http://www.visibletechnologies.com/resources/white-papers/adverse-events/
About the Author

Siddhesh Dhuri is an Associate Consultant with Wipro Technologies in the Analytics and Information Management division. As part of his current role, he follows trends in Post Marketing Analytics in the Pharmaceutical and Medical Devices industry. He is the subject matter expert on Social Media in the Pharmaceutical Industry.

He has around five years of experience in the IT industry out of which 4 years is in the Pharmaceutical domain. His areas of interest include consulting, business development, social media and marketing analytics.

Prior to joining Wipro, Siddhesh worked as a Technology Analyst at Infosys. He holds bachelor’s degree in Computer Engineering from Mumbai University and an MBA in Marketing from Great Lakes Institute of Management.

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