Engage with confidence: Managing online adverse event reporting

Ensuring digital engagement between healthcare companies and their consumers aligns with regulatory requirements
Introduction

The healthcare industry, and, specifically, consumer health companies, are waking up to the enormous potential offered by social media and other online data sources to make better informed decisions around brand, product development and commercialization.
Finding the healthcare industry’s needle in the electronic haystack

The mention of adverse events through online chatting by consumers on social media could be causing healthcare executives to have sleepless nights. However, the phenomenon actually pre-dates the Facebook generation by some time.

“Adverse events have been reported by people on the internet ever since there were chat rooms or an ability to post online,” says Joy Liu, a partner at law firm Ropes & Gray, suggesting the issue first reared its head in the early 1990’s.

So how big is this problem for the consumer health industry? Initially, the regulatory risk from direct two-way online dialogue was clear. “There was recognition that if consumer health companies let people leave comments on one of their pages, the company, having viewed these comments, would therefore be obliged to respond and take action,” elaborates Liu, resulting in early online consumer healthcare-related activities being mostly didactic one-way communication.

As the digital space has evolved, healthcare gradually ventured further into online dialogue, with forums and Facebook pages offering an opportunity to build connectivity with healthcare professionals and consumers. In 2011, however, companies could no longer “turn off” comments in their Facebook pages, leading companies to withdraw from the channel completely. Slowly and uncertainly they have returned, but it is to an environment where the reporting of online adverse effects is not straightforward. The challenges in managing adverse events tracking within social media remain, despite guidance published in 2014 by:

- The FDA on ‘Fulfilling regulatory requirements for post-marketing submissions of interactive promotional media’
- The AESGP to ‘promote self-regulatory mechanisms to ensure appropriate and effective monitoring and implementation’

Recognizing that the industry faces a number of difficulties around taking a responsible and compliant approach towards tracking online adverse events, Siva Nadarajah, General Manager, Nexxus Social at IMS Health, started working to identify solutions to two main challenges.

Firstly, the high volume of comments from online channels potentially makes screening and tracking of adverse events difficult.

Secondly, adverse events from such unstructured data sources are not always obvious, with Nadarajah highlighting that “identifying these adverse events and a lack of clarity on those cases where you cannot identify the consumer” can cause problems.

It is something the regulators are grappling with, too. Whilst the easy answer might be to simply apply existing adverse event reporting guidelines to online activities, in practice this is ambiguous. For example, guidelines from the US regulators state that four criteria must be met for a reportable adverse event:

1. An identifiable consumer
2. An identifiable reporter
3. A suspect product
4. An adverse experience or fatal outcome suspected to be due to the product consumed
In reality, only some of these criteria may be met with online comments. For example, an anonymous forum poster would not fulfil criteria (1) or (2), even with a clearly reported side effect and product. Some companies take a proactive stance and actively seek the missing information but data protection can be an issue here. “If a consumer has purposefully commented from a closed profile we have to be careful not to infringe privacy”, says Nadarajah. As a result, Liu notes that healthcare companies prefer to manage these issues offline and “would much rather have someone call the hotline so that the person answering the phone can ask them all the relevant questions”.

After years of waiting for the FDA to provide some clarity on the subject, the recent draft guidance is helpful in that it says that companies are only responsible for the content that they produce or sponsor on behalf of their brands. However, this doesn’t resolve the issue of how to run effective and compliant post-marketing surveillance activities on the online content they are responsible for.

Case studies shaping the approach for AE tracking in the social media space

THE CHALLENGE

- Monitor adverse events generated in Facebook user comments in real-time and report to global drug safety within 1 hour of the comments being posted on a Facebook wall.
- Client ruled out 100% manual human monitoring due to anticipated volume of data.

THE SOLUTION

- AETracker was implemented to detect adverse events, off-label usage and product mis-information in real-time.
- IMS Health drug safety experts were employed to validate the triggered adverse events for drug safety, 24/7.

RESULTS & CLIENT BENEFITS

- Brand engagement with consumers was positively impacted
- Manual inspection done by the client’s drug safety team validated that all adverse events were properly captured by the software
- The fan base grew to 200,000 within 3 months, a record for a healthcare brand
Calculating a true risk-benefit profile

Lack of clear regulations is not, however, the major concern for the healthcare industry. It is the perceived overwhelming volume of adverse event reports online that causes the anxiety.

So whilst monitoring online brand mentions can provide useful information to consumer health companies, Nadarajah describes how the “benefit–to–risk ratio of gathering information from online sources, then using it for marketing intelligence, is perceived to be high on the risk side”.

In order to test the real scale of online adverse event reporting and challenge this perception, Nadarajah got involved in a study tracking posts relating to a leading brand over a 12-month period. During this time 11,246 posts were picked up that mentioned the specific brand. These posts were spread across a variety of sources (see Figure 1) including blogs, forums, social channels and news alerts.

What was the volume of reportable adverse events identified from these posts? There were 211, just 1.8% of the total posts. “It is a figure that is representative of other studies”, says Nadarajah. “You see about 2% of the conversations will have reportable adverse events pretty much across all over-the-counter (OTC) categories”. Even if you look for reports that do not meet all criteria, the figure is still relatively low, with typically 7–8% of posts falling into this group that should be tracked but not reported.

Figure 1: Total posts mentioning a specific healthcare brand over a 12 month period and breakdown by channels.
The real challenge, Nadarajah explains, is not therefore the total volume of adverse events, but being able to quickly identify the relatively small number of adverse events from large amounts of data. “The problem for consumer health companies has been identifying out of 10,000 or 100,000 posts, which are the adverse events. Without the proper technology, someone has to read all these posts,” he says. An unenviable job for anyone!

The role of technology in managing online adverse events

The solution, Nadarajah believes, lies in using the right technology to quickly and efficiently sift through this enormous volume of data to identify and report adverse events that meet some or all of the regulatory criteria. In order to do this, any technological solution must be able to:

- Interrogate different sources and formats of potentially unstructured data
- Know what language/key terms to look for when searching for adverse events
- Allow users to efficiently review the outputs and form links between associated data pieces that individually might not constitute a reportable adverse event

Whilst there are numerous tools that can rapidly screen online data for specific terms and present the outputs in a user-friendly format, the most complex aspect relates to the second point – knowing exactly what language to look for when searching for adverse events. “Here technology plays a very important role,” says Nadarajah. “You need a new set of taxonomies, a new set of ontologies, which can understand how a consumer describes a side effect on Facebook, for example. This requires historical data collection and a very rich dataset that can capture every single description of an adverse event, every single variation of it, misspellings and abbreviations that people use in social media.”

Without this rich data library derived from historically studying how people talk about side effects online, it is like looking for a needle in a haystack without knowing what the needle looks like. It is here that most ‘non-healthcare’ specific technologies fall down. This is a problem Nadarajah has spent three years focusing on, slowly developing a ‘side effects lexicon’ for each disease state by observing the conversations of consumers, doctors and pharmacists. With this piece in place, the rest flows seamlessly.

Without it, the downstream process may appear seamless but, like a slick forecasting model with bad data inputs, it is fundamentally flawed.

What is interesting is that the language-driven technology can be applied to ‘offline’ data too, such as market research reports or representative data from a CRM system. “As long as you can process one unstructured dataset, you can process any unstructured dataset,” Nadarajah explains.
Can adverse event monitoring be totally automated?

Nadarajah is unequivocal in his response: “No, 80% of the work is automated and 20% is manual. We are not going to eliminate the human factor.” Even with the best natural language processing dictionary and the smartest technology, the process is not perfect. What is important is that the technology is not missing any potential adverse events and is being overcautious, so human intervention is still needed to review the outputs.

“The human’s job is to eliminate false positives because the automated process will always pick these up to ensure the pharmacovigilance department is not being bombarded with too much data. However, the automated process ensures no genuine positives are missed,” he explains. So this synergy of adverse-event, language-trained technology and medically trained human beings, allows for an efficient and compliant process that is not overwhelming.

Ultimately the way in which Nadarajah views managing adverse event reports can be compared to the way in which doctors manage their patients. The number one rule for a doctor is ‘do no harm’, which equates to the number one rule for Nadarajah to ‘do not miss any adverse events’. Beyond that, it is about optimizing the process of managing adverse-event reporting which allows consumer health companies to do the constructive work it wants to do online, without fear of a call from the regulators.

Social media listening gets consumer health talking

Is online adverse event monitoring purely about mediating risk or could it have a more significant impact on healthcare?

Nadarajah sees the potential here but is philosophical about where the industry is right now and the time it will take to steer a course into less reactive work. “Healthcare is mainly using this technology as a compliance necessity around brand or promotional campaigns or market research activities,” he explains. “I have not seen a lot of companies proactively looking for adverse events in social media as an early warning of problems because they have not been sure about the guidelines”.

Within healthcare, the benefits of broader social media activities, including listening to customers in relation to specific products, are being embraced mostly by companies with a strong OTC presence, Nadarajah says. One large OTC company invested considerably in a Facebook page that became a case study at a recent Facebook conference on how a regulated company used its site and saw a 10% uptake in sales. As he points out, OTC brands are regulated very much like prescription drugs, with stringent requirements around reporting side effects and off-label usage. The difference here is that these companies see the benefits of being closer to their consumers and use social media as a tool, rather than a hindrance, to engaging with their consumers.
Listening leads to talking

The old adage of having ‘two ears and one mouth’ certainly applies to the consumer health industry with regards to social media. Most companies are, at least, monitoring some online dialogue relevant to their brands, even where they are not proactively engaging, Nadarajah observes. “With the OTC example on Facebook, the company’s call center volume significantly dropped because consumers were using the site to ask questions or report adverse events. It is about the best way to provide customer service as social media is changing the relationship between consumer health companies and their consumers,” Nadarajah explains.

Looking further ahead, he believes such activities could further assist the consumer health industry in refining the positioning of its products. This is something other industries, such as the fast-moving consumer goods industry, have wholeheartedly embraced. “This could open up a whole new business model as consumer health companies realize they can find out much earlier about the efficacy of a brand, or how it is being used by consumers, in addition to much earlier knowledge of potential incidents related to the brand,” Nadarajah says. The pathway from “listening” can lead to improved consumer engagement and using the information from this engagement to adapt commercialization strategies and business models (see Figure 2).

Certainly, the offline activities of the consumer health industry have shifted to reflect a more consumer-centric approach of recognizing the value of input, at both the research and commercialization stages of development, in delivering products that meet consumer needs. The same benefits could be amplified by taking these discussions online.

Figure 2: There are benefits to moving beyond listening in to deeper engagement with consumers, whereby their feedback can be applied to adapt both commercialization strategies and business models.
Conclusion

In conclusion, Nadarajah is keen to reinforce that it is easy to see the digital world, particularly with regards to social media, as a separate realm. However, the benefits and risks outlined above apply to all kinds of engagement between healthcare industry players and their consumers, as does the technology.

“Adverse events monitoring is not just about social media; the technology can be applied to any unstructured data that healthcare companies are using – offline or online,” he explains.

So the technology behind online adverse event monitoring is not just about mitigating the risk of digital activities. It is about changing the way the consumer health industry interacts with its consumers in a much broader space.

The risks have been clearly documented by many and experienced by an unfortunate few, but the benefits are only just starting to be realized. And with an efficient process for highlighting those adverse event “needles in the haystack”, consumer health companies can not only start to really engage with its end-user consumers, but can also feed their research and commercial activities from the wealth of consumer data that exists online.
This white paper was adapted from a series of interviews with Siva Nadarajah of IMS Health by Paul Tunnah of pharmaphorum, first published in September 2013.

Siva Nadarajah is General Manager, Social Media at IMS Health and joined the organization through the acquisition of Semantelli, which he co-founded and grew to be an industry recognized leader in social analytics for healthcare. Prior to founding Semantelli, Siva was responsible for global CRM and compliance solutions with Cegedim. Siva is a voting member of the Wikimedia Foundation and has spoken worldwide about adverse events management in social media and the impact of Wikipedia in healthcare. He was recognized for uncovering two major security holes in Microsoft Hotmail in the early days of the Internet, which forever changed the security design of internet based email systems.

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IMS Health would like to acknowledge the contribution of Joy Liu, a Washington–based life sciences partner with Ropes & Gray. She represents pharmaceutical, biotechnology, and medical device companies on a broad range of FDA regulatory issues.
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About IMS Health

IMS Health is a leading global information and technology services company providing clients in the healthcare industry with comprehensive solutions to measure and improve their performance. End-to-end proprietary applications and configurable solutions connect 10+ petabytes of complex healthcare data through the IMS One™ cloud-based master data management platform, providing comprehensive insights into diseases, treatments, costs and outcomes. The company’s 15,000 employees blend global consistency and local market knowledge across 100 countries to help clients run their operations more efficiently. Customers include pharmaceutical, consumer health and medical device manufacturers and distributors, providers, payers, government agencies, policymakers, researchers and the financial community.

As a global leader in protecting individual patient privacy, IMS Health uses anonymous healthcare data to deliver critical, real-world disease and treatment insights. These insights help biotech and pharmaceutical companies, medical researchers, government agencies, payers and other healthcare stakeholders to identify unmet treatment needs and understand the effectiveness and value of pharmaceutical products in improving overall health outcomes. Additional information is available at www.imshealth.com.