Dissecting DDMAC’s NOV Letter on Content Sharing

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Overview

On July 29, 2010, the Division of Drug Marketing, Advertising, and Communications (DDMAC) of the U.S. Food and Drug Administration (FDA) issued a notice of violation letter to Novartis indicating that communications created by a social media sharing widget on several Tasigna® websites violated the Federal Food, Drug, and Cosmetic Act and FDA implementing regulations. The letter was made public August 5, 2010.

According to PubMed, Tasigna® is a kinase inhibitor “used to treat certain types of leukemia (cancer that begins in the white blood cells) in people whose disease could not be treated successfully with imatinib (Gleevec®) or people who cannot take imatinib.” Tasigna® labeling carries a black box warning.

The details of the letter indicate that the Facebook sharing feature of the social widget on the Tasigna® U.S. website generated communications that were in violation because they:

- Failed to provide risk information (omission of risk)
- Broadened Tasigna® indication beyond what was approved (broadening of indication)
- Implied advantages of Tasigna® over other products (unsubstantiated superiority claims)
- Implied the drug is more effective than clinical experience or evidence has proven (overstatement of efficacy)

The letter also pointed out that, while the website itself was submitted to FDA per regulations, the shared content was not submitted prior to use (failure to submit).

Understanding Metadata

Popular free social sharing widgets include tools such as ShareThis (used by Novartis in this case), AddThis and AddToAny. These widgets allow visitors to click a button located on a website, generating a message that is then posted to a social media site such as Facebook or Twitter. These widgets often operate by reading metadata contained in the source code of the page. Metadata consists of a series of meta tags, each of which provides information about attributes of the page such as page title, a description of the content and key words used by search engines. These meta tags are not visible to users but can be read by social tools and search engines. The example below demonstrates how metadata generates search engine results and social messages.

When social widgets read the metadata, they generate a message that a user can approve to be posted to the selected social media site. This can be problematic to the pharmaceutical industry in several ways:

- Metadata is sometimes overlooked as an important element of internal site legal/medical/regulatory review processes. This may have been the case with Novartis, since the rest of the Tasigna site seemed to have been in compliance.*
- Metadata and content used to create the message can exceed the character limitations of the social media widget.
• Metadata and content used to create the message can exceed the character limitations of the social media site. For example, Twitter allows 140 characters; Facebook allows 420.

When the character limitations are exceeded, only a portion of the approved message is delivered. Note, metadata can be controlled by the pharmaceutical company, but character limitations on sites, such as Facebook, cannot.

As a result it is important to select a social sharing tool that does not construct the message from traditional metadata. Instead, a better solution is to select a tool that allows enhanced control over the message. As shown in the example below, the optimal social sharing tool doesn’t rely on traditional metadata.

In addition, the message posted did not contain any disclosure of risk, and, as the letter states:

“Tasigna® is associated with a number of serious risks, as detailed in the Boxed Warnings, Contraindications, Warnings and Precautions, and Adverse Reactions sections of the PI. … Promotional materials, other than reminder pieces, which include the name of the drug product but do not include indications or other representations or suggestions relative to the drug product (see 21 CFR 200.200, 201.100(f), 202.1(e)(2) (i)), are required to disclose risk and other information about the drug. Such materials are misleading if they fail to reveal facts that are material in light of the representations made by the materials or with respect to consequences that may result from the use of the drug as recommended or suggested by the materials.”

It is possible the metadata provided may have been too long for the character limits of the social sharing widget. As a result, the full indication information was trimmed, making it appear as though Tasigna® is appropriate for a broader range of indications. And the risk information may simply have been too long to be included at all.

It is also possible that the metadata was overlooked altogether as content that needed to be reviewed and addressed, and in fact may never have matched what FDA feels should have been represented. Novartis’ legal/medical/regulatory committees may not have had any idea that this metadata existed and therefore had not reviewed nor submitted it. One example captured in the FDA letter from the Tasigna® professional site reads, “More information to Support your Patients.” Most legal/medical/regulatory committees would not allow the inconsistencies in upper and lowercase letters in “Support” and “Patients.”

Another possible explanation is that Novartis or one of its partners chose to shorten the metadata in order to save space and, in doing so, accepted a certain amount of risk that we now know was unacceptable.**
Whatever the root of the problem, by confirming that safety information must be included in any social media message, other than reminders, the FDA is applying the same standard to social media as it has to other forms of pharmaceutical communications, such as the infamous 14 NOV letters for search marketing in 2009.

Analyzing Social Sharing
Because of the clarifications provided in the letter, it is imperative that the pharma industry understands the nature of social sharing.

Things to Understand Regarding Social Sharing in Pharma

1. The first step for pharma to share content in social channels is to clearly understand the product and what limitations must be taken into account. Unbranded content, for example, will have fewer sharing restrictions. Branded content – especially for black box drugs – requires a thorough analysis of the product and regulations surrounding it. In this case, FDA has clarified that established regulatory rules apply to social sharing just as they do any other pharmaceutical communication.

2. Some organizations are already analyzing metadata from a perspective of improving search engine optimization (SEO), but because sharing tools commonly create the shared message by combining the title and description meta tags, careful analysis of all metadata is becoming a crucial requirement. Therefore, if pharma companies are not already scrutinizing the metadata that is applied to each page of content, it’s time to start.

3. Next, companies should reach out to their partners and thoroughly analyze any social sharing solutions. The reality is that most social sharing options are developed with commercial websites and blogs in mind and are not designed to address the complex communication regulations applied to the pharmaceutical industry. For this reason, it is important to work with your digital agency partners to find the best solution for your product.

4. The next step is to understand any limitations of the target social media site where the content will be shared. Facebook, for instance, places a 420-character limitation on status updates. If a shared message exceeds 420 characters, Facebook will trim the message, which could result in delivery of content that does not meet regulatory restrictions.

5. The final step in pharma social sharing is to create a message that meets the now-known regulatory restrictions of the FDA. In some cases a message that contains full indication may exceed character limits and may not be appropriate for sharing. This means brands must analyze all social sharing activities on a content-by-content basis (by page, or even by paragraph), as opposed to at the site level. Additionally, it’s possible that there are branded messages, such as those for black box drugs, that simply won’t be suitable for sharing using a social media widget.

Understanding the Implications
The industry has asked for clarity around the use of social media in promotional marketing. While the untitled letter has severe implications for many companies currently using social sharing tools, it does provide clarity on several key points.

Implications for Pharma

1. Pharma must follow the known rules. The same rules apply in social media when it comes to indication, fair balance, efficacy, superiority claims, submission, etc. Pharma cannot afford to be careless – even with “invisible” metadata. If the Tasigna® metadata content had not been shortened by the social sharing tool, would Novartis still have gotten the letter? It’s quite possible.
2. The myth of the “one-click” rule-that-was-never-a-rule has been, once again, discredited and debunked. In reviewing the verbiage in the warning letter, FDA is clearly re-emphasizing that the practice of having safety information “one click away” is not acceptable and does not meet regulatory requirements.

3. Pharma and its partners must understand the limitations of all social media tools. While the FDA letter calls out Facebook specifically, in actuality, the issue was with the ShareThis sharing widget – not a “Facebook Share social media widget” as FDA stated. Either way, it’s important to note the implications of the letter reach all social sharing tools and even other situations where there are space limitations (such as search and mobile). Pharma must work with strong, tech-savvy partners who can help them understand the limitations of the Internet and social media tools.

4. When issuing letters, FDA has always carefully considered the source of the content. In this context, FDA did not seem to have a problem with user-generated content, acknowledging “Facebook users can add additional comments that are displayed separately from the Tasigna® information.” The letter all but implied that once the information is shared and out of pharma’s control, pharma is not liable.* Again, the key for companies will be to make sure the content that is within the company’s control is in line with current regulation. Although the line is a gray one, FDA has taken a step toward defining where culpability stops and starts in pharma social media.

5. Pharma’s use of social is not dead. There likely will be more letters – and, it is hoped, eventually guidance – that will contribute to a framework of more clarity around the use of social media promotional materials. In truth, this is exactly what the industry has been asking for. After the initial reaction subsides, perhaps regulatory teams will feel more comfortable moving forward in the social space.

**Recommendations**

Pharmaceutical companies’ initial reaction to the letter may be to question social media as a viable communication channel for pharma. We feel it is important that companies resist this temptation and instead focus on how they can adjust their digital communications to meet the regulatory guidelines set forth by FDA. By following these five steps, companies can take immediate action to help ensure social sharing activities are in compliance.

**Our Recommendations to Ensure Social Sharing Compliance**

1. Conduct a full review of all existing websites, including sites from marketing, corporate, public affairs, microsites, landing pages, live sites and those currently in review. With the new information from the FDA letter, it is time companies take a hard look at all online properties and re-evaluate the risks and benefits of users sharing content. If using social sharing tools like AddThis, ShareThis or AddtoAny, companies should make sure information and messaging being shared is compliant. They should remove sharing tools that are in violation and ensure that social sharing activities are in compliance.
2. Conduct a review of content and metadata. Take a close look at each piece of content and determine how that content is represented in sharing tools and search engines. Depending on the tool, the message may be created by the use of metadata or may be created by "scraping" your site for the content that will eventually be shared. Any content that violates FDA regulations should be adjusted or sharing functionality should be removed. And a review of metadata should be worked into all internal review processes if it isn’t already.

3. Make adjustments to sharing strategy. This is not the time to retreat from social sharing. Once companies have reviewed all materials and determined what content is in violation or in compliance, it’s time to course-correct the sharing strategy. The FDA has clarified that the same rules that govern other pharma communications apply to social sharing as well. Social sharing is still a valuable way to spread the message about your product, condition or campaign, and can still be a useful tool when it meets regulatory compliance.

4. Work with your trusted partners to find a solution that adheres to pharma regulations. There are new options beyond the typical free social sharing tools, which tend to truncate information or share inappropriate metadata. Intouch Solutions is in the final stages of testing a social sharing tool designed specifically to address the needs of the pharma industry. It will allow our clients to customize what is shared and will take into account both pharma regulations and social site limitations to provide a safer social sharing experience for the end user.* If you are interested in learning more about our solutions, contact Intouch Solutions.

5. Think about the big picture. Social media is not going away and the FDA letter issued to Novartis is not a game-changer. Nor is it a justification to stop using social media. Instead, it has provided clarification as to the appropriate use of social sharing and has provided an opportunity for companies to refine their overall marketing strategy. By adjusting social media strategies to include these clarifications, marketers can better serve consumers, professionals and regulatory requirements.

Conclusion
While the communications that were shared by Novartis on social sites like Facebook did not meet the communication requirements set forth by DDMAC, it is important to understand that this letter is not indicating that the use of social sharing widgets or social media sites is prohibited. Instead, the letter is indicating that messages delivered using social sharing tools must meet the already established regulatory guidelines, despite space limitations.

It should be noted that social sharing is still an important piece of any digital marketing strategy. The good news is, tools will be available that will help alleviate these issues by taking pharma regulations into account. Understanding pharma content regulations and selecting the appropriate tool to control the message will ensure that social sharing continues to be a viable way to spread the message about pharma products, conditions and campaigns.

Intouch will continue to monitor the issues surrounding social sharing and keep clients informed, as new developments are available.

* Intouch Solutions is providing this information to clients and partners in an attempt to help interpret information provided by FDA through the July 29, 2010, untitled letter. While not regulatory, legal, or medical experts, the Intouch Solutions associates and authors of this paper are well versed in the pharmaceutical industry and digital technologies, especially social. Content above should be considered informational and opinion-based. Each individual company should assess its own policies, procedures, and level of risk tolerance when considering any social media strategy.

** To be clear, Novartis is not a client of Intouch Solutions, and Intouch Solutions has no knowledge of or ties to which decisions were made by Novartis and its partners in this situation.

What We Recommend:
1. Remove sharing functionality that is in violation.
2. Review metadata – now and from now on.
3. Re-visit social sharing strategy.
4. Work with a trusted partner to find a solution.
5. Remember the big picture.

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